

Government of Pakistan
Ministry of NHR&C
Islamabad Healthcare Regulatory Authority

Islamabad, the 08th December, 2021

NOTIFICATION

IHRA/BoAM-17/4-121/2021 The following draft Minimum Service Delivery Standards Regulations, 2021, proposed to be made by the Islamabad Healthcare Regulatory Authority, in exercise of the powers conferred under section 4 sub-section (1) read with Section 10 sub section 1(e), section 16 sub-section 1(c) and section 47 sub-section (1) & (2) of the Islamabad Healthcare Regulation Act, 2018 (XXIII of 2018), is hereby published for information of all persons likely to be affected thereby and notice is hereby given that comments, if any, received within fifteen days of the date of this notification will be taken into consideration.

DRAFT MINIMUM SERVICE DELIVERY STANDARDS REGULATIONS, 2021

1. **Short title, application and commencement-** (1) These regulations may be called the Minimum Service Delivery Standards Regulations, 2021.
(2) Every healthcare establishment or healthcare professional providing healthcare services within Islamabad Capital Territory under the provisions of Islamabad Healthcare Regulation Act, 2018.
(3) These shall come into force on the date of their publication in the Official Gazette.
2. **Definitions.** — (1) In these regulations, unless there is anything repugnant in the subject or context: -
 - i. “Act” means Islamabad Healthcare Regulation Act, 2018 (XXIII of 2018);
 - ii. “Standards” means Minimum Service Delivery Standards (MSDS) as specified in the schedules to these regulations;
 - iii. “healthcare establishment” means as defined in the Act;
 - iv. “healthcare professional” means as defined in the Act;
 - v. “healthcare services” means as defined in the Act;
 - vi. “Schedule” means a Schedule to these regulations.

(2) The words and expressions used but not defined in these regulations shall have the same meanings as are assigned to them in the Act.

3. **Measurable criteria** (1) For the purpose of measuring, monitoring and regulating the healthcare services' quality levels provided by the healthcare establishment or healthcare professional, all the healthcare establishments and healthcare professionals shall maintain the standards as prescribed in the schedules to these regulations.
 (2) Authority shall take all measures to make compliance with the standards specified in the schedules to these regulations.
4. **Penalty for contravention of the standards.** Authority shall take action and impose penalties, according to provisions of the Act or rules and regulations made under the Act, against any healthcare establishment or healthcare professional, as the case may be, for non-compliance of the standards specified under these regulations.

SCHEDULE

- (i) Different standards have been made under these regulations for the different healthcare establishments providing different healthcare services, all these healthcare establishments shall be required to maintain standards as per relevant Schedule mentioned hereunder applicable to them:

Sr. No.	Category	Schedule
1.	Minimum Service Delivery Standards for Hospitals	Schedule-I
2.	IHRA Standards for Primary Health Care Facility	Schedule-II
3.	Minimum Service Delivery Standards For Clinical Labs	Schedule-III
4.	Minimum Service Delivery Standards For Dental Clinics	Schedule-IV
5.	Minimum Service Delivery Standards For Psychiatric & Addiction Treatment / Rehabilitation Facilities	Schedule-V
6.	Minimum Service Delivery Standards For Tibb	Schedule-VI

SCHEDULE-I

IHRA Standards for Hospitals

1 SCOPE

This IHRA Standards prescribe the service management and service provision standards for hospitals. These standards provide the basis for organizational assessment of the delivery of quality patient care and services, and utilization of available resources. These standards are applicable to all types of hospitals – public and private, large and small, urban and rural. Each standard is described through indicator(s), which are color coded as red (critical) and yellow (not mandatory or part of minimal requirement).

2 NORMATIVE REFERENCES

IHRA 1001:2020 IHRA Standards for Hospitals

3 TERMS AND DEFINITIONS, AND ABBREVIATIONS

For terms and definitions, please see IHRA 1010:2020 (IHRA Standards – Terms and Definitions on Healthcare).

MANAGEMENT OF HOSPITAL

4.1 Mission and Strategic Planning

Standard 1: The hospital is directed and managed effectively and efficiently in accordance with its objectives and mission statement.

Indicator 1: Mission statement is available.

Indicator 2: The mission and values are available and disseminated to the staff and general public in languages and forms appropriate to the local population and their needs.

Indicator 3: Goals and objectives of the services are reflected in the strategic plan.

Indicator 4: Policies and annual plans are in line with strategic plans.

4.2 General Management

Standard 2: Responsibilities for operating the organization, managing its resources and for complying with applicable laws and regulations, which are clearly documented.

Indicator 5: There is a Governing Board for the hospital.

Indicator 6: Governing Board must be responsible for establishing and reviewing of mission goal, setting quality culture, resources, legislation and monitoring and evaluation of achievement of strategic and annual plans.

Indicator 7: Hospital In-charge has appropriate qualification and requisite experience.

Indicator 8: Job descriptions clearly defines accountability and responsibility of the in-charge.

Indicator 9: Current Organizational Chart identifies the chain of communication.

Indicator 10: Organizational chart are reviewed and communicated to the relevant staff.

Indicator 11: Mechanisms are defined within hospital for internal and external services.

Indicator 12: Staff follows the policies of confidentiality and release of information.

Indicator 13: Scope, roles and functions of each clinical services/unit/department are stated.

Indicator 14: Each service in the hospital is led by an identified manager with appropriate qualification and experience.

Indicator 15: Duty rosters are published at least two weeks in advance.

4.3 Risk and Quality Management

Standard 3: The hospital prevents and manages risks, identifies opportunities to continuously improve its processes and services, makes improvements and evaluates their effectiveness.

Indicator 16: Risk management plan for safe healthcare delivery is available.

Indicator 17: Incidents, accidents, near misses and adverse events/reactions are reported and recorded.

Indicator 18: Body for Continuous Quality Improvement (CQI) meets on regular basis.

Indicator 19: Quality group develop plan for CQI with defined roles and responsibilities.

Indicator 20: Performance indicators for priority diseases and key processes are available.

Indicator 21: Regular assessment is conducted of patient satisfaction on key process.

Indicator 22: Policy and procedures are developed with inputs of the staff. **Indicator 23:** Staff follows documented policies and procedures.

Indicator 24: Appropriate and evidence based clinical guidelines are available.

Indicator 25: Staff is trained to follow the guidelines.

Indicator 26: Clinical audit and its process is agreed between management and clinical staff.

Indicator 27: The effectiveness of the improvement plan is evaluated.

Indicator 28: Sufficient financial resources are allocated for CQI.

4.4 Financial Management

Standard 4: Financial resources are managed efficiently and effectively in order to optimize services that can be provided and results can be achieved.

Indicator 29: A qualified Financial Manager is responsible for developing rules and procedures for financial management

Indicator 30: In-charge (Medical Superintendent, CEO, Director or COO) and departmental heads are involved for setting annual targets for the budgets of the financial years

Indicator 31: Accounting system is in place to indicate revenues and expenditures

Indicator 32: Internal control audit system is in place.

Indicator 33: External financial audit is undertaken on annual basis.

Indicator 34: A mechanism is used to safeguard of assets in accordance with financial rules and regulation.

4.5 Human Resources Management

Standard 5: Staff are appointed, trained, evaluated and promoted in accordance with documented procedures, job descriptions and service needs.

Indicator 35: The hospital develops and implements policies and procedures for the management of staff, which includes appointment, selection, training, appraisal,

promotion, and retention of appropriately qualified staff to meet the service objectives of the organisation.

Indicator 36: Staff availability and skill mix are consistent with the on-going role and functions of each unit.

Indicator 37: Records are available which show:

- Staff levels and skill mix
- Workload and complexity
- Sickness and absence
- Training

Indicator 38: Staff appointments are made in line with the required qualification and experience for the job.

Indicator 39: Staff is treated in accordance with an equal opportunities policy and as per Government rules.

Indicator 40: Current job descriptions and responsibilities for all staff are available and all staff has a copy of their job description.

Indicator 41: All new staff has their professional registration papers checked on appointment and regularly thereafter to ensure employees have a current valid registration with the relevant professional accreditation body.

Indicator 42: All staff is oriented to the hospital and their specific positions through a documented induction program.

Indicator 43: The induction programme includes:

- The hospital's mission, values, goals and relevant planned actions for the year
- Services provided
- Roles and responsibilities
- Relevant policies and procedures, including confidentiality
- Use of equipment
- Safety
- Emergency preparedness
- Quality improvement

Indicator 44: Every staff member in the hospital can be identified by appropriate mechanisms, E.g., uniforms, name tags, hats.

Indicator 45: Staff performance is evaluated annually with the staff member against their job description and agreed targets and is used to identify strengths, areas for improvement and training needs.

Indicator 46: The hospital identifies staff authorised as competent to undertake admissions, carry out assessments, provide treatment in different services and maintain and manage waiting lists.

Indicator 47: Student nurses, doctors or other health professionals are supervised by a qualified nurse, doctor or other health professional as appropriate.

Indicator 48: There are appropriate facilities for staff representatives including access to a meeting room.

Indicator 49: A training needs assessment exercise is conducted every two years with the objective of developing training plans for all staff groups in order to meet the development needs of individual health professionals and the service needs of the organisation.

Indicator 50: A continuing education programme is accessible to all staff. Participation is encouraged and monitored by the hospital.

Indicator 51: There is a training budget, which is calculated to allow appropriate training to take place.

Indicator 52: Accurate and complete personnel records, including records of training, are kept in a secure location and treated as confidential.

Indicator 53: Key indicators such as absenteeism and staff turnover are measured and the results analysed and used for improvement.

5 PATIENT RIGHTS

5.1 Information for Patients

Standard 6: Patients have the right to receive all information relevant to their care management to enable them to make informed decisions.

Indicator 54: Patient right and responsibility charter is developed and displayed in patient area.

Indicator 55: There is documented process to inform about patient rights.

Indicator 56: Guidance and advice is provided at the registration point.

Indicator 57: There is display of information in reception area and wards about the rights of the patients, services and facilities available in the hospital, cost of services, and feedback and complaints pathways.

Indicator 58: Information on hospital areas is displayed at prominent places through appropriate signage.

Indicator 59: Patient and their families are informed about the status of their health and clinical conditions.

Indicator 60: Information is provided about the treatment and its cost, effects, side effects and alternatives.

Indicator 61: Written consents are obtained about the invasive procedures.

Indicator 62: Up to date evidence-based information is provided for disease prevention and health promotion.

Indicator 63: Relevant health messages are displayed at prominent places.

Indicator 64: Patients have informed choices and preferences.

Indicator 65: Precautions and information about the hospital's responsibility of personal belongings.

Indicator 66: An interpreter is available at the hospital.

5.2 Patient Feedback on Services

Standard 7: Patients have the right to complain about the services and treatment and their complaints are investigated in a fair and timely manner.

Indicator 67: Patients are informed about their right to express their concerns or complains verbally or written.

Indicator 68: Patients are provided with mechanisms for submission of complaints.

Indicator 69: The progress of the complaint investigation must be shared with patient.

Indicator 70: Documented process of complaint handling and the patients are informed about the progress.

Indicator 71: The results of the complaints investigation are submitted on monthly basis and used for quality improvement.

5.3 Privacy and Dignity of Patients

Standard 8: Patients' privacy and dignity are respected throughout the entire care process.

Indicator 72: Patient has right of individual bed.

Indicator 73: Consultation, treatment room and washing facilities allow privacy.

Indicator 74: In-patient changing facilities are appropriate and allow privacy.

Indicator 75: No procedure is carried out in presence of unconcerned person.

Indicator 76: Processes are in place to identify and respect of values and beliefs of patients.

Indicator 77: The patients are relieved of pain and suffering according to current knowledge.

Indicator 78: The needs of end-of-life care is assessed and documented.

Indicator 79: Staff is made aware of the needs of end-of-life care.

SERVICE DELIVERY

6 CARE CONTINUUM

6.1 Access to Health Services

Standard 9: Services are continuously available and the hospital minimizes physical, economic, social, cultural, organizational or linguistic barriers to access.

Indicator 80: Access ways and passageways are kept clear at all times.

Indicator 81: Functional, clean and disinfected wheel chairs and stretchers are available at the gate/reception for patients who are unable to walk.

Indicator 82: Hospital should avoid cross infections of patients while ensuring infection prevention practices at all places

Indicator 83: All patient areas of the hospital are easily accessible by wheelchair.

Indicator 84: Multi-storey buildings have ramps or functional lifts with an operator.

Indicator 85: The hospital and its departments are clearly signposted and a site plan is displayed at a central place for orientation of staff and patients.

Indicator 86: A reception with a male and female receptionist to guide the patients is open during operating hours.

Indicator 87: The hospital specifies visiting hours and communicates these to the public.

Indicator 88: Rules for numbers and kind of visitors and attendees are clearly defined and visibly posted and facilities to enable relatives to sit at the bedside and to stay overnight if needed.

Indicator 89: Documented policies and procedures for prioritizing the patient examination and treatment, bed availability, referrals, waiting time and support to special persons

Indicator 90: On admission to hospital, patients are introduced to the nurse on duty and given an orientation to the unit to which they are admitted including the location of toilets, pantry and other facilities and services.

Indicator 91: Patients admitted to the hospital have access to an allotted bed with fresh linen and do not have to double up with other patients.

Indicator 92: Elective admissions, including waiting list management and cancellations are managed in accordance with documented policies and procedures and based on patient need.

6.2 Continuity of Care

Standard 10: Patients have the right to continuity of care, including cooperation between all health care providers and/or establishments which may be involved in their diagnosis, treatment and care.

Indicator 93: Every patient is registered and issued the appropriate form for recording various details of symptoms, diagnosis, treatment and services being provided.

Indicator 94: All patients and visitors to the hospital receive courteous and prompt attention from the staff at reception and in ward or department.

Indicator 95: The doctor on duty has primary responsibility for the clinical care of any patient until a specialist takes over.

Indicator 96: The nurse on duty is responsible for patient assessment, care planning and evaluation of care in coordination with other care providers and services.

Indicator 97: A stock of essential drugs is available at all times in each treatment area

Indicator 98: Doctors, qualified nurses and appropriate support staff are available on-site 24 hours per day.

Indicator 99: There should be clear processes for nurses to summon urgent medical help if required.

Indicator 100: Regular meetings of different care providers are held to share information on patients' progress and patient care is formally handed over with the transfer of all relevant information when staff changes duties.

Indicator 101: The patient's record is available to all care providers.

Indicator 102: Planning for discharge or end of service begins at admission and involves the patients and their family and potential providers of follow-up services.

6.3 Assessment

Standard 11: *All patients have their health care needs identified through an established assessment process.*

Indicator 103: Assessments are carried out by qualified professionals identified by the hospital as competent to do assessments.

Indicator 104: Criteria to prioritise emergency patients exist and are implemented.

Indicator 105: Patients' choice regarding examination by a male or female is respected as far as possible.

Indicator 106: A nurse/chaperon is available when patients are being examined by members of the opposite sex.

Indicator 107: An assessment of the patient's needs is systematically completed on an agreed form including, for example, medical, psychological, social, physical, environmental, educational, spiritual and cultural needs.

Indicator 108: The initial assessment includes the recording of vital signs, weight, height and significant findings.

Indicator 109: The patient's relatives and carers are included in the assessment by providing information wherever possible.

Indicator 110: A history and full medical examination is entered in the patient records by a member of the medical staff as soon as possible but within maximum 6 hours of admission. All patient assessments should preferably be reviewed and approved by the attending consultant within 24 hours of admission.

Indicator 111: After examining the patient, the doctor legibly endorses the assessment findings, records the provisional diagnosis and the course of action on the OPD card or the patient record and dates and signs it.

Indicator 112: Except in an emergency, admission notes are completed prior to any surgical procedure.

Indicator 113: Following examination, written as well as verbal information is provided for patients regarding future visits, treatment and medication.

Indicator 114: Patients are re-assessed at certain intervals to determine their response to treatment and to plan for continued treatment or discharge and re-assessment results are documented in the patient's record.

6.4 Care Planning, Monitoring and Evaluation

Standard 12: *Health Care Providers develop and implement a written, up-to-date plan of care/service for each patient and monitor the care provided against this plan.*

Indicator 115: A written care plan for each patient is prepared in collaboration with the patient, carers/relatives and other appropriate health professionals.

Indicator 116: Care plans identify the goals of care and treatment and reflect the patient's assessed needs, perceptions and priorities, agreed philosophy of care, current practice guidelines and evidence-based practice.

Indicator 117: The care plan includes how the patient's individual choices and preferences are to be addressed.

Indicator 118: The care plan is evaluated and updated in accordance with the findings of re-assessment and progress in meeting identified goals.

Indicator 119: The care plan is used by doctors, nurses and other health professionals to facilitate continuity of care and on-going appropriate treatment.

Indicator 120: Outcome indicators, e.g. hospital acquired infections, bedsores, leg ulcers, LOS, falls, errors and patient complaints, are systematically monitored, recorded, analysed and used to improve care.

6.5 Treatment

Standard 13: The organization delivers services to the patients that meet their individual assessed needs, reflect current best practice and are coordinated to minimize potential risks and interruptions in provision.

Indicator 121: Clinical guidelines/treatment protocols are used to guide patient care processes.

Indicator 122: Policies and procedures guide the care of high-risk patients, such as:

- emergency patients
- those who are comatose or on life support
- those with communicable diseases or who are immune suppressed
- patients on dialysis
- vulnerable elderly and children
- Seriously ill patients

Indicator 123: Written procedures to ensure that the right medication is administered to the right patient. These must include:

- Identification of the patient before medications are administered
- Verification of the medication and the dosage amount with the prescription
- Verification of the routes of administration
- Verification of the time of administration

Indicator 124: Medication effects (including adverse effects) and medication errors are monitored, reported and analysed.

Indicator 125: Parental medication must be given under strict aseptic conditions, observing hand hygiene

Indicator 126: Appropriate and sufficient manpower, equipment and support services are available to allow nursing staff to meet the care needs of patients, with at least one nurse present round the clock.

Indicator 127: Patients are not disturbed unnecessarily except for medical reason.

6.6 Documentation of Care

Standard 14: The patient record contains sufficient information to identify the patient, support the diagnosis, justify the treatment and care, document the course and results of the treatment and care, and promote continuity of care among health care providers.

Indicator 128: A clinical record is initiated for every patient admitted to the hospital and wherever possible there is only one set of case notes for each patient.

Indicator 129: Patient records are maintained through the use of a unique number or other form of identification unique to the patient.

Indicator 130: Entries in the patient records are legible, dated, signed and identifiable.

Indicator 131: The use of symbols and abbreviations is kept to a minimum in accordance with an agreed list of abbreviations within the hospital.

Indicator 132: There is an agreed format for filing of information within the patient record.

Indicator 133: The hospital respects information about a patient's health status, medical condition, diagnosis, prognosis and treatment and all other information of a personal kind as confidential, even after death. Confidential information is only disclosed if the patient gives explicit consent or if the law expressly provides for this.

Indicator 134: The patients' record can be used for research purposes only if the patient has given a written consent and/or if there is an approval by the Ethics Committee.

Indicator 135: The original patient record may not be removed from the hospital premises, except by court order. Policies and procedures are in place to prevent the loss and/or misuse of patient records.

Indicator 136: The patient record is sufficiently detailed to enable the patient to receive effective coordinated treatment and care and includes:

- Details of admission, date and time of arrival

- Patient assessment and medical examination
- Sheet containing history pertinent to the condition being treated including details of present and past history and family history
- Diagnosis by a registered health professional for each entry to the hospital
- Details of the patient care or treatment plan and follow-up plans
- Diagnostic test orders and results of these tests
- Progress notes written by medical, nursing and allied health staff to record all significant events such as alterations in the patient's condition and responses to treatment and care
- Record of any near misses, incidents or adverse events
- Medication sheet recording each dose given
- Treatment record
- Observation charts, E.g., temperature chart, input and output chart, head injury chart, diabetic chart
- Specialist consultation reports
- Mode of discharge, E.g., left against medical advice or discharged on request
- In case of death, details of circumstances leading to the death of patients

Indicator 137: For surgical patients, the clinical record additionally includes anaesthetic notes, operation record and consent form.

Indicator 138: Where referrals have been made, the patient record includes the referral letter and indications for referral.

Indicator 139: An 'alert' notation for conditions such as allergic responses to medications or food, adverse drug reactions, radioactive hazards and infection risks is prominently displayed in the record.

Indicator 140: A completed discharge summary signed by the doctor (full name) who authorized the discharge is submitted to the records department within 72 hours of the patient's discharge.

Indicator 141: All diagnoses/procedures are coded using international standards and a yearly summary report is prepared and used for planning.

Indicator 142: Patient records (hard copies) are retained for a minimum of 7 years and disposed of according to existing rules and legislation.

Indicator 143: All patient records should preferably be saved in a computer system and be available for perpetuity.

Indicator 144: Appropriate policies and procedures are in place to govern access to and storage of patient records.

Indicator 145: There is a clear policy which allows patients access to their records.

Indicator 146: All patient records are filed in a central medical record filing / computer system.

Indicator 147: There is a provision of a separate storage area for keeping medico-legal case records.

Indicator 148: There is a system for easy retrieval of records.

Indicator 149: The storage area for patient records is protected against fire, flooding and damage by insects consistent with the Govt. of Pakistan norms.

Indicator 150: A tracking system monitors the removal, movement and replacement of patient records between internal users and the Medical Records Department.

6.7 Discharge, Transfer and Referral

Standard 15: Safe and appropriate discharge, transfer or referral of patients is based on the patient's health status and need for continuing care.

Indicator 151: A written and dated procedure including criteria to determine readiness for discharge, transfer or referral of patients is used and specifies who is authorised to do it.

Indicator 152: Reasonable time, preferably 12 hours, of notice of discharge or transfer is given to patients and carers.

Indicator 153: Follow up arrangements, agreed with the patient and/or the family, and are noted in the patient record prior to discharge.

Indicator 154: On discharge, the attending doctor summarises in the patient record the primary (and secondary) diagnosis, any complications, any operative procedures undertaken and any follow up arrangements agreed with the patient/family.

Indicator 155: A discharge card/slip containing relevant information such as reason for admission, findings, diagnosis, treatment, medication, condition at discharge, date of discharge and name of attending practitioner is signed and given to the patient and/or his family prior to discharge, with a copy retained in the patient record.

Indicator 156: The patient and/or the appropriate carer or attendant is advised on any necessary skills for care after discharge such as moving and handling techniques or catheter care.

Indicator 157: If patients are transferred to another hospital or doctor, copies of their clinical notes and the discharge slip accompany them to provide sufficient information for continuity of care and feedback

Indicator 158: Patients being transferred to other facilities are provided with necessary resources such as transport, walking aids and documentation.

Indicator 159: Before transfer the facility to which the patient is being transferred is informed about receiving the patient, their status and the time of arrival and afterwards the hospital checks with the facility that the transfer has been safely made.

7. OPERATION THEATRE DEPARTMENT

7.1 Service Management

Standard 16: Operation Theatres provide safe, hygienic and appropriate services for patients and are coordinated with other services of the hospital to provide continuity of care.

Indicator 160: The operation theatre(s) and/or department are managed by a suitably qualified, registered and experienced nurse, doctor or senior operating department assistant.

Indicator 161: A list of hospital-approved surgical procedures, equipment and other inputs and processes is communicated to staff.

Indicator 162: Anaesthetic services are provided by qualified, registered and experienced anaesthetists.

Indicator 163: An anaesthetist is present / available for all surgical procedures 24 hours a day.

Indicator 164: A designated, suitably trained member of staff (Operating Theatre Assistant, anaesthesia technician) is available to assist the anaesthetist at all times.

Indicator 165: A visiting consultant surgeon or assistant provide surgery, assistance and advice through a signed agreement specifying the limits of their consultation.

Indicator 166: Regular documented audits of the operating theatre are carried out and the information is used by relevant management, safety and/or quality improvement committees.

Indicator 167: Any changes required to practice, provision or organisation as a result of the audits are discussed with all staff concerned before implementation.

Indicator 168: Coded data available to OT staff from audits includes:

- Admissions and discharges by speciality
- Diagnosis-specific bed utilisation
- Procedure-specific operating rates
- Post-operative infections
- Post-operative deaths
- Unplanned return to theatre
- Post-operative pulmonary embolism

- Post-operative CVA
- Post-operative cardiac myocardial infarction
- Unplanned re-admission within 28 days of discharge
- Unplanned transfer to ICU
- Unplanned transfer to another unit
- Unplanned second operation within 6 weeks of surgery
- Damaged organs following surgical procedure

Indicator 169: Mechanism/process of patients' safety is in place and followed, including:

- Identification of the right surgical site
- Swab and instruments counting before incision and stitching

7.2 Policies, Procedures and Records

Standard 17: *Operational policies and procedures clearly describe the key processes of the Operation Theatre and/or department, the responsibility of the staff and expected results, and records provide accurate information for analysis and evaluation.*

Indicator 170: Written up-to-date procedures are available, followed by staff and include but are not limited to the following:

- Signage of OT as a restricted area and identification of persons allowed in the OT
- Sterilisation and identification of sterilised OT equipment
- Separation and transport of dirty linen
- Pre-operative assessment and instructions
- Routine equipment checks and preparation
- Annual review of functioning equipment in line with the services offered by the OT
- Sending for and the transportation of patients from ward to OT
- Admission to the operating department
- Identification of patients
- Identification of operation site
- Recovery
- Inoculation injury
- Staff protection against exhaust from anaesthetic gases
- Post-operative care
- Handover procedures for pre-operative and post-operative patients
- Diathermy use
- Tourniquet use
- X-ray use
- Laser use
- Swab, needle and instrument count
- Infected patients

Indicator 171: The following formal documentation/records are available in the department:

- Theatre register (anaesthesia register and surgeons' register)
- Prosthesis register
- Electro medical equipment register
- Record of correct swab/instrument count
- Controlled drugs
- Specimens register
- Record of weekly/monthly analyses of surgeries (including the ICD 10 code)
- Next-day schedule for operations
- Maintenance of stock levels of drugs and consumables
- Duty roster

Indicator 172: Specific safety rules and instructions are displayed and followed by staff for the following:

- Storage and use of hazardous chemicals, E.g., glutaraldehyde, formalin
- Storage and use of compressed gases
- Appropriate shielding and protective clothing, E.g., for image intensification
- Emergency electrical power supply (UPS, inverters, generators and emergency electric lights)

Indicator 173: Surgical patients are managed by surgeons, anaesthetists and nurses with appropriate qualifications and experience.

Indicator 174: Children have (the right of) access to a parent prior to and during induction of anaesthesia, and during recovery.

Indicator: All patients undergoing surgery are identified by a bracelet or other unique identification method secured to the patient.

Indicator 175: Full, non-abbreviated preoperative notes are kept for all patients and include but are not limited to:

- Signed evidence that informed consent to surgery has been obtained by a doctor for critical surgery and by the nurse for routine surgery
- Signed evidence that the correct procedure was followed when obtaining consent for children under the age of 18 years
- Details of the site and side of an operative procedure

Indicator 176: There has a separate fully functioning and equipped recovery room.

Indicator 177: A trained recovery nurse is present for each anaesthetic session and remains in the recovery area until the last patient has been discharged back to the ward.

Indicator 178: Sufficient, qualified and experienced staff monitoring patients in the recovery room to ensure individual patient supervision at all times.

Indicator 179: Documented discharge criteria are used to assess patients' readiness to leave the recovery room.

Indicator 180: The anaesthetist is available in the hospital until the patient has recovered from anaesthetic.

Indicator 181: The anaesthetist provides the final authorization for the patient to leave the recovery area.

Indicator 182: There are clear, formal instructions on how to contact a doctor in an emergency.

Indicator 183: A documented visit is made to each in-patient at least once by the surgeon, anaesthetist or doctor between the first post-operative day and discharge.

Indicator 184: A record of the operation for the patient record is made immediately following surgery and a copy is retained in the OT. The record includes the following:

- Date and duration of operation
- Anatomical site/place where surgery is undertaken
- The name of the operating surgeon(s), operating assistants including scrub nurse and the name of the consultant responsible
- The coded diagnosis made and the procedure performed
- Description of the findings
- Details and serial numbers of prosthetics used
- Details of the sutures used
- Swab and equipment count
- Immediate post-operative instructions
- The surgeon's and scrub nurse's signatures

Indicator 185: Anaesthetic records contain:

- Date and duration of anaesthesia
- Name of surgical operation performed
- The name of the anaesthetist, anaesthesia assistant and, where relevant, the name of the consultant anaesthetist responsible
- Pre-operative assessment by the anaesthetist
- Drugs and doses given during anaesthesia and route of administration
- Monitoring data
- Intravenous fluid therapy
- Post-anaesthetic instructions
- Any complications or incidents during anaesthesia
- Signatures of anaesthetist and anaesthesia assistant

7.3 Facilities and Equipment

Standard 18: Safe and adequate facilities and equipment are provided to meet the needs and volume of patients undergoing procedures in the operating theatre(s).

Indicator 186: Arrangements are made so that hospitals OTs are situated separately from areas accessible to the general public.

Indicator 187: Hazard and/or warning notices are clearly displayed before restricted and high-risk areas.

Indicator 188: Changing facilities are provided for theatre staff to enable those entering the theatre to not cross “dirty” areas.

Indicator 189: Separate male and female changing and rest rooms are available.

Indicator 190: There is a clear separation of ‘dirty’ areas in OT(s) and only persons wearing theatre dress enter the OT(s).

Indicator 191: Staff uses a separate space for maintaining records and other office activities.

Indicator 192: The anaesthetic induction area/room and operating theatre are equipped with safe and well-maintained equipment specific for OT activities including but not restricted to the following:

- Anaesthetic machine and ventilator
- Laryngoscopes
- Endotracheal tubes/laryngeal masks
- Airways
- Nasal tubes
- Suction apparatus and connectors
- Oxygen
- Drugs and IVs required for planned anaesthesia
- Drugs for emergency situations
- Monitoring equipment including ECG, ETCO₂, temperature monitoring, pulse oximeters and blood pressure
- Accessible defibrillator
- Anaesthetic gas scavenger system
- Tipping/tilting trolleys/beds
- Multi positioned table with radiolucent tops
- Suction machine
- Instrument cleaning/decontamination facilities
- Temperature and humidity control
- IV Cannulas and CV lines in different sizes
- Blood warmer

- Adequate light sources
- Special equipment for particular age groups, E.g., neonate resuscitation table

Indicator 193: A list of additional items needed for special procedures and surgeries carried out by the OT is available in the theatre.

Indicator 194: The recovery area is well lit and adjacent to the operating theatre.

Indicator 195: Resuscitation equipment and drugs are immediately accessible in the recovery area.

Indicator 196: A list of functioning equipment available in the recovery room includes:

- Airways (Ambu bags) and other intubation material and equipment
- Suction
- Oximeter
- ECG
- Tipping/tilting trolleys/beds
- Blood pressure measurement apparatus
- Defibrillator
- Anaesthesia machine
- Oxygen concentrator
- Emergency ventilator

8 EMERGENCY SERVICES / CASUALTY DEPARTMENT

8.1 Service Management

Standard 19: The Casualty Department provides safe, timely and efficient live-saving emergency care and minor treatment and surgery for patients.

Indicator 197: The casualty department is managed at all times by a suitably qualified and experienced nurse, doctor or senior casualty department assistant.

Indicator 198: Deputising arrangements for suitably qualified and experienced deputies are documented and used.

Indicator 199: A signed agreement and close professional links with other emergency units offering more comprehensive services enables the provision of necessary emergency services.

Indicator 200: Data and outcome indicators are systematically recorded and aggregated for analysis. These include a documented review of volume of activity, source and appropriateness of referrals and adverse events.

Indicator 201: Data available for clinical review includes:

- Number of attendances
- Repeat visits
- Patients who died in the casualty department

8.2 Policies, Procedures and Records

Standard 20: *Operational policies and procedures clearly describe the key processes of the casualty department, the responsibility of the staff and expected results. Records provide accurate information for analysis and evaluation.*

Indicator 202: Written procedures and guidelines are used consistent with the policy for:

- Identifying which patients should be seen immediately by a doctor in the department
- How medical help is summoned in emergency
- Dealing with life threatening emergencies before medical help arrives
- The transfer of patients
- The transfer of records
- The use of Tele-medical techniques

Indicator 203: The hospital disaster plan clearly identifies the role, procedures and individual staff responsibilities within the casualty department in the event of a nearby major incident or disaster.

Indicator 204: All patients are seen within fifteen minutes of arrival for initial assessment and treatment prioritisation.

Indicator 205: Each patient is informed of the approximate waiting time after the need for treatment has been assessed.

Indicator 206: A process is used to monitor patient waiting times.

Indicator 207: Patients are examined in privacy by a doctor of the same sex as the patient (if available), or have the service of a chaperone if desired.

Indicator 208: Relatives are kept informed of the patient's condition with the agreement of the patient where they are able to give such consent.

Indicator 209: Locally agreed policies and procedures, consistent with local and/or national guidelines, are used for:

- All major acute emergencies commonly falling in the scope of hospital.
- Road traffic accidents
- Major incidents
- Assault
- Domestic violence
- Child protection

- Rape
- Psychiatric emergencies
- Drug abuse
- Suspected criminals
- Suspected victims of crime
- Police enquiries
- X-ray requests
- Requests for reports
- Tetanus immunisation
- Death in the unit

Indicator 210: An individual record of attendance is completed which contains:

- Name
- Address
- Age/Date of birth
- Next of kin
- Occupation/School
- Case number
- Telephone number
- Date and time of arrival
- Time of examination
- Diagnoses
- Treatment
- Minor surgery carried out
- Specimens taken
- Instructions for follow up
- Doctor's or nurse's names and signatures
- Medication given to/or taken away
- Advice given on discharge

Indicator 211: A departmental register identifies all attendances, reason for attendance, diagnostic tests, treatment given and any referrals.

Indicator 212: A formal mechanism (roster) known to all staff is used for identifying medical staff on duty and on call and is prominently displayed in the emergency care area.

Indicator 213: A procedure exists for referral for specialist care if necessary.

Indicator 214: An agreed policy is followed which defines under what circumstances, if any, nurses may issue or administer specific drugs (including tetanus toxoid) without a specific doctor's order.

Indicator 215: The type and extent of minor surgery to be undertaken is defined and is consistent with the facilities, equipment and skills available on site.

Indicator 216: A written, dated, signed policy on the referral, selection and treatment of patients for minor surgery is followed.

8.3 Facilities and Equipment

Standard 21: Safe and adequate facilities and equipment are provided to meet the needs and volume of patients attending the emergency services /casualty department.

Indicator 217: A mechanism exists for regular review of the design and appropriateness of the treatment facilities and medical and surgical supplies to assess whether they are sufficient for the work undertaken in the unit.

Indicator 218: The casualty entrance is clearly signposted from outside the hospital.

Indicator 219: A call bell is available if the entrance to the unit is locked.

Indicator 220: Parking is available for patients, including designated space for the disabled.

Indicator 221: There is a canopy over the casualty entrance used by ambulances.

Indicator 222: The doorways and access are suitable for wheelchairs and trolleys.

Indicator 223: Emergency alarms are strategically sited within the unit to summon help.

Indicator 224: Contemporary basic clinical textbooks and information are available for staff.

Indicator 225: There is appropriate equipment for:

- Resuscitation
- Monitoring
- Minor operations
- Sterilisation
- X-rays and other imaging (either locally or by referral)

Indicator 226: Hallways, clinical and public areas are clear of equipment, beds or other obstructions.

Indicator 227: Treatment areas afford the patients' privacy.

Indicator 228: A private area/room is available for interview and examination.

Indicator 229: The waiting area:

- Has drinking water facility
- Has comfortable and adequate seating
- Is clean and secure

Indicator 230: There are toilet facilities suitable and available for males, females and disabled.

Indicator 231: A public telephone is available for the use of patients and relatives.

9 INTENSIVE CARE UNIT

9.1 Service Management

Standard 22: The Intensive Care Unit is managed by suitably qualified staff and organized to provide safe and efficient care for seriously ill patients who need to be continuously monitored.

Indicator 232: A qualified professional with relevant training in intensive care is responsible for overall co-ordination of the unit and is accessible for specialist advice.

Indicator 233: A designated deputy is responsible for the management of the ICU in the absence of the manager.

Indicator 234: An appropriately qualified, registered and experienced nurse is responsible for the day-to-day management of nursing care in the unit.

Indicator 235: Staff is allocated on the basis of a systematic analysis of patient dependency and number of patients.

Indicator 236: All staff working in the unit are appropriately qualified and experienced for the work they do and have attended specialist high dependency care courses and continuous medical education for updating their skills.

Indicator 237: Registered nurses in the unit have completed formal in-service training or a recognised course in intensive care and at least one is present on all shifts.

Indicator 238: A suitably experienced doctor is immediately available at all times.

Indicator 239: The Unit has a person who leads on infection control issues.

Indicator 240: Relevant current texts are available for all staff for reference on the unit.

Indicator 241: The expenditure/cost of procedures in the ICU is clearly defined, and available.

9.2 Policies and Procedures

Standard 23: Operational policies and procedures which clearly describe the key processes of the ICU, the responsibility of the staff and expected results are followed by staff.

Indicator 242: Specific policies and procedures include emergency admission to ICU from:

- Theatres
- Wards
- Other departments
- Outside

Indicator 243: Management policies and/or procedures are available and followed by staff for the following:

- Airway management
- Conscious Sedation
- Ventilators/respirators
- Central oxygen supply and oxygen cylinders
- CVP readings (central venous pressure)
- Infusion pump management
- Pulse oximeters
- Cardiac monitors
- Arterial lines
- X-ray and other imaging investigations
- Epidural care
- Recovery facilities for all surgical cases where there is no dedicated recovery unit
- Recovery care of major surgical cases

Indicator 244: Specific emergency procedures are available and followed for:

- Apnoea/respiratory arrest
- Cardiac arrest
- Laryngeal spasm/stridor

Indicator 245: There are written criteria defining who is authorised to perform the following emergency clinical activities:

- Intubation
- Tracheotomy
- Insertion of central lines
- Defibrillation

Indicator 246: There are written policies and procedures agreed and followed for the following:

- Clothing of staff and visitors
- Filtering of patients' respired air
- Changing of catheters, humidifiers and ventilator tubing
- Isolation of at-risk or infected patients

- Cleaning of the unit

Indicator 247: Regular meetings take place to review cases and patient management, both within the unit and in conjunction with other departments.

Indicator 248: The Unit discourages open visiting.

9.3 Facilities and Equipment

Standard 24: Safe and adequate facilities and equipment are provided to meet the needs and volume of patients in the ICU.

Indicator 249: There is sufficient space for storing disposable and consumable items.

Indicator 250: A functional resuscitation trolley and defibrillator are available on the unit

Indicator 251: Within the Unit, a designated member of staff is responsible for checking and recording daily and after each use.

- Resuscitation equipment
- Stockholding and date of resuscitation drugs

Indicator 252: Each bed has a central line facility for:

- Oxygen
- Suction
- Compressed air
- Central ECG monitoring

Indicator 253: Beds in the unit are arranged to allow ready access for routine and emergency procedures and are within direct vision of supervising staff at all times.

Indicator 254: Adequate (at least three) numbers of power sockets are available for each bed.

Indicator 255: Facilities in the unit include:

- CVP monitoring
- Pulse oximetry
- Blood pressure monitoring (automatic)
- Urometry
- Ambient and patient temperature monitoring
- Arterial blood gases
- Glucometer
- Electrolyte machine

10 RESUSCITATION

10.1 Service Management

Standard 25: All professional staff is trained in resuscitation at least to basic life support levels. Those working in higher risk areas, E.g., casualty department, operation theatres and ICU are trained in advanced life support.

Indicator 256: There is a written, agreed description of the scope and operation of resuscitation services provided within the Hospital.

Indicator 257: A resuscitation training team exists within the Hospital and is responsible for the co-ordination of procedures, equipment and training of health staff both in the hospital and in the community.

Indicator 258: The provision of resuscitation conforms to the recommendations of the Health Department and/or international guidelines.

Indicator 259: There is a formal mechanism for obtaining specialist clinical advice on resuscitation issues.

Indicator 260: There is a programme for regular in-service training of clinical staff in handling equipment and procedures for resuscitation throughout the hospital.

Indicator 261: Records on training status are maintained for individual staff members.

Indicator 262: All medical staff has received advanced resuscitation training at least every three years, by a trainer who has undertaken a recognised course and documentation is provided to show evidence of this.

10.2 Policies and Procedures

Standard 26: Policies and procedures related to resuscitation exist and are known to the staff.

Indicator 263: Policies and procedures are reviewed as necessary but at least once year.

Indicator 264: An agreed, defined clinical procedure for resuscitation of adults (and children, if appropriate) exists and is followed by the staff.

Indicator 265: An agreed, defined policy for when to use a defibrillator exists and is followed.

Indicator 266: There is an agreed and written policy on the training of staff in the use of a defibrillator.

Indicator 267: There is a policy for providing paramedic and medical assistance for resuscitation to the community.

10.3 Facilities and Equipment

Standard 27: The Hospital provides adequate and functioning equipment for resuscitation in emergencies.

Indicator 268: Within the hospital, a designated member of staff is responsible for the checking and recording daily and after each use:

- Resuscitation equipment
- Stockholding and date of resuscitation drugs

Indicator 269: Facilities available for resuscitation include:

Mechanical

- Resuscitation trolley containing equipment and medication for advanced life support
- Defibrillator
- Laryngoscopes (including for children, if appropriate)
- Suction apparatus
- Manual ventilation equipment E.g., bag, valve-mask, pocket mask
- ECG monitor and leads
- **Supplies** (including for children if relevant)
- Intravenous infusion sets
- Endotracheal tubes and/or laryngeal masks
- Oral airways
- IV Cannula

Medications

1. Oxygen

- Intravenous fluid
- Resuscitation drugs.

Indicator 270: All equipment is checked on a daily basis and after each use by suitably qualified staff. Records of the checks are kept with the equipment and monitored.

Indicator 271: Endotracheal Intubation, cricothyroidotomy set and chest drainage equipment is only used by those experienced and trained in their use.

Indicator 272: Facilities (equipment) are conveniently located within the hospital to be accessible to highest risk patients.

11 MATERNITY SERVICES

11.1 Service Management

Standard 28: Maternity services provide safe, timely and efficient maternity care for patients.

Indicator 273: The maternity department is managed by a suitably qualified, registered and experienced.

Indicator 274: Deputising arrangements for suitably qualified and experienced deputies are documented and used.

Indicator 275: A signed agreement and close professional links with a referral hospital offering more comprehensive services ensures provision of necessary emergency maternity services not available in the hospital.

Indicator 276: The maternity department has 24 hour on-site cover from qualified medical doctors and an anaesthetist.

Indicator 277: Consultant obstetricians provide assistance and advice through a signed agreement.

Indicator 278: Data for clinical audits and reviews is collected, analyzed and used for quality improvement activities and includes:

- Relevant quality indicator.
- Number of women in ante-natal clinics
- Number of women with medical or surgical disorders in ante-natal clinics
- Number of women transferred to higher-level care during pregnancy
- Number of deliveries
- Number of live and still births
- Perinatal mortality figures
- Maternal mortality figures
- Number of transfers to specialist care during labour
- Number of still births
- Birth Registration records
- Number of Caesarean sections
- No. of difficult labour cases

11.2 Policies, Procedures and Records

Standard 29: Operational policies and procedures clearly describe the key processes of the maternity unit, the responsibility of the staff and expected results. Records provide accurate information for analysis and evaluate

Indicator 279: Written procedures and guidelines are used consistent with the hospital policies and functions for:

- Ante natal care and booking/registration
- Post-natal care
- Perinatal care
- Counselling for parenthood (e.g. family planning, genetic referral)
- Identifying high risk pregnancy
- Admission to labour room/ward
- Planning, treatment and mode of delivery
- Plan for managed pain during labour and delivery
- Delivery monitoring process
- Referral
- Discharge including discharge summary
- Birth record and certificate
- Labour register
- Immunization for mother and baby
- Infection control
- Disposal of placentas

Indicator 280: A paediatrician is involved in the team developing and reviewing policies and procedures.

Indicator 281: Each woman accessing the maternity department is cared for by a suitably qualified, registered and experienced nurse, doctor or senior midwife who she can contact for advice and help throughout her pregnancy.

Indicator 282: Anaesthetists with relevant qualifications and experience available for mothers with epidural, C Section, emergency breech and instrumental deliveries, emergency resuscitation and women with eclampsia.

Indicator 283: A trained mid-wife/nurse is present at every birth.

Indicator 284: A record of regular training in maternal and neonatal resuscitation is kept in the department for medical and nursing staff attending deliveries

Indicator 285: A guideline on requesting medical assistance at any time during labour is used by nurses and midwives

Indicator 286: A roster indicates 24-hour arrangements for on-site availability of a suitably qualified and experienced doctor and an anaesthesiologist in case of an emergency.

Indicator 287: Separate records are initiated and used for each baby.

Indicator 288: Records kept after discharge, include the combined:

- Maternity notes (including care plans)
- Birth registration(s)
- Labour register
- Admission register
- Neonatal and perinatal morbidity
- Neonatal and perinatal mortality
- Maternal morbidity and mortality

11.3 Facilities and Equipment

Standard 30: *Facilities and equipment are safe and adequate in design and number for the purpose and quantity of patients attending/in the maternity department.*

Indicator 289: The delivery room is equipped with functioning, safe and well maintained equipment specific for deliveries including but not restricted to the following:

- Fetoscope
- Ultrasound machine
- Delivery table which can be turned to the trendelenburg position
- An anaesthetics machine with emergency oxygen supplies
- Endotracheal tubes, laryngoscope
- An incubator, with temperature adjustable for infants in need
- Separate oxygen supply to the incubator
- Resuscitation equipment and drugs for infants and for adults
- Intravenous crystalloid and plasma expanders
- Weighing machine for the baby

Indicator 290: Privacy for mothers is possible, e.g. when breast-feeding.

Indicator 291: A separate room for seriously ill or intensive patients, e.g. eclampsia, is available.

Indicator 292: The area for labour provides for:

- Space for the woman and a female companion
- Alternative birthing methods
- Ambulation throughout labour
- Washing and toilet facilities for the comfort of the mother and companion

Indicator 293: Lighting is versatile enough to provide a restful environment and allow birthing procedures to be performed.

Indicator 294: The post-natal ward provides sufficient room for babies to room-in with mothers.

Indicator 295: Nursery facilities with an even temperature and humidity are available, and are adequate in size with appropriate supplies and equipment for teaching mothers about caring for their babies.

AUXILARY SERVICES

12 LABORATORY SERVICES

12.1 Service Management

Standard 31: The medical testing laboratory is managed and organised to provide efficient and effective laboratory care to patients and support services to clinicians.

Indicator 296: The medical testing laboratory is managed by a suitably qualified and registered pathologist, experienced medical technologist or other suitably qualified and registered laboratory scientist.

Indicator 297: A suitably qualified deputy is designated in the temporary absence of the laboratory manager.

Indicator 298: Sufficient and appropriately qualified staff is available to fulfil the job descriptions of the defined service.

Indicator 299: Laboratory staff participates in the health and safety committee, hospital quality committee and other relevant committees.

Indicator: Departmental staff attends meetings of appropriate advisory /consultative bodies and have input into decisions affecting the laboratory.

Indicator 300: A pamphlet outlines the list and prices of services offered the types of specimen's required and approximate reporting time for tests.

Indicator 301: Laboratory staff inform in writing the designated hospital infection control committee of any infection identified in in-patient samples that could provide a risk to the hospital staff or patients.

Indicator 302: The service has a continuing education programme for staff development enabling staff to meet the needs of the hospital, the department, the individual and the patients.

Indicator 303: Staff follows written policies and procedures for collection, transport and controlling, storing, reporting and disposing of all samples and tests in compliance with legal requirements.

Indicator 304: Staff is involved on a regular basis in a quality management programme to monitor and improve the laboratory quality

Indicator 305: Any outstation laboratory equipment is subject to the same quality control procedures as in the main laboratory.

Indicator 306: The department has planned and systematic activities for the monitoring and evaluation of its services.

12.2 Samples and Tests

Standard 32: Laboratory samples and tests are managed to maximize accuracy of testing and minimise risks to patients and staff.

Indicator 307: A requisition form is used and includes the following:

- Patient information
- Patient location
- Investigations required
- Type of sample
- Clinical
- Probable diagnosis
- Requesting physician
- Sample collection time
- Name of phlebotomist

Indicator 308: Staff follows and communicates to patients, verbally and in writing, procedures for the patients' preparation for tests.

Indicator 309: Samples collected are labelled with the patient's name, registration number, date and time of collection.

Indicator 310: Separate labels are used for high-risk samples.

Indicator 311: Specimen trays are designed to enable safe transport.

Indicator 312: The sample reception area receives, records, and verifies the samples or specimens.

Indicator 313: A laboratory registers records:

- Patient name, location
- Identification of sample source(s)
- Full name of the investigation(s)
- Number of investigations
- Investigation results

Indicator 314: Samples are safely and accurately distributed to the respective sections of the laboratory.

Indicator 315: Results are recorded in the laboratory register and on the reporting/result form.

Indicator 316: Patient Results Registers are readily accessible to staff.

Indicator 317: Results are made available to the main reception of the laboratory to enable picking up by OPD, wards or patients.

Indicator 318: Signed and dated SOPs for each test and patient preparation for each test are readily available to staff in the laboratory.

Indicator 319: Staff follows written, dated and signed procedures for:

- Patient preparation for tests
- Completion of test request forms
- Reporting of test results
- Reporting results verbally
- Dealing with out-of-hours test requests
- Investigating transfusion reactions
- Emergency and urgent requests
- Storage of specimens and blood on the wards and in other departments
- Dispatch of samples to other laboratories
- Posting of samples
- Acceptable parameters for response to test requests and reporting times

Indicator 320: Staff follows written procedures for samples:

- Sample collection
- Handling
- Labelling
- Transportation
- Retention
- Storage
- Disposal of samples, including blood and body fluids

Indicator 321: The service is able to give expert advice on:

- The appropriateness of tests
- The samples required
- The interpretation of results
- Further recommended tests

Indicator 322: Instructions are clearly displayed describing the safe disposal of clinical, toxic and radioactive waste.

Indicator 323: Clearly labelled, separate containers are used for disposal of hazardous and infectious waste.

Indicator 324: A written agreement exists, and staffs follows this agreement, between the hospital and external laboratory covering all aspects of tests including time scales for reporting results.

Indicator 325: A written policies/ procedures Critical or unexpected findings are discussed with the referring doctor.

12.3 Safety

Standard 33: *All persons are protected from potential hazards in the laboratory.*

Indicator 326: A mechanism is in place to restrict access to the laboratory to authorised personnel only.

Indicator 327: Health and safety policies, current relevant hazard notices and safety action bulletins are displayed as required or are readily available to staff, including but not limited to:

- Safety regulations
- Fire precautions
- AIDS/HIV/
- Hepatitis

Indicator 328: Appropriate equipment is used for the safe handling of hazardous materials.

Indicator 329: Action to be taken in the event of an infection emergency is known to all staff and is clearly stated in writing.

Indicator 330: Staff is offered immunisations relevant to their type of work and emergency immunisations based on written policies.

12.4 Facilities and Equipment

Standard 34: *Safe and adequate facilities and equipment are provided to meet the needs and volume of patients served by the laboratory.*

Indicator 331: Laboratory and office space are sufficient to enable staff to carry out their jobs safely.

Indicator 332: The laboratory environment is well lit ventilated.

Indicator 333: Staff has access to sufficient laboratory equipment to carry out their jobs safely.

Indicator 334: Storage facilities for specimens and reagents are sufficient to enable staff easy access.

Indicator 335: Refrigerated storage facilities are used for specified samples, specimens, and blood samples.

Indicator 336: Functioning emergency electrical supply for refrigerators is available and there is a procedure in place to regularly assess its readiness.

Indicator 337: Inspection, calibration and maintenance schedules are completed and used for all laboratory equipment.

Indicator 338: Staff facilities include:

- Locker space
- Toilet and washing/shower facilities
- Staff rest room
- Overnight accommodation for on call staff

RADIOLOGY

13.1 Service Management

Standard 35: Radiology services are managed and organised to provide safe and efficient care for patients and support to clinical specialties.

Note: Radiology services cover all services provided by a radiology department.

Indicator 339: A radiologist is responsible for the clinical direction of the department and the safety of the patients.

Indicator 340: Radiology services are administered by an identified qualified, registered radiologist or radiographer with clearly defined responsibility for all non-clinical aspects of the department.

Indicator 341: Trained, qualified radiographers, or in some cases radiologists, are the only staffs who may take images.

Indicator 342: There are on-call staffs for mobile radiography and other imaging at all times.

Indicator 343: Radiation protection is supervised by the radiologist and monitored by the Hospital in-charge and the Nuclear Regulatory Authority.

Indicator 344: Staff follows written policies and procedures for all aspects of radiology services, including:

- Reception and registration of the patient
- Preparation of the patient for imaging

- Processing and interpreting the film or scan
- Reporting on the film or scan
- Documentation and despatch

Indicator 345: Up to date reference manuals, radiation regulations and guidelines, radiation safety reports, are available within the department.

Indicator 346: The department participates in the Hospital's quality improvement system and monitors the quality of its services using an internal quality control programme which includes:

- Equipment utilisation review
- Performance checks on equipment, including processors
- A record of maintenance checks for all items of equipment
- Film and scan reject rates
- Clinical audit
- Turnaround times for the reporting of films and scans

Indicator 347: Radiology Department takes action on the results of its quality control programme, in a radiology quality committee and participate in the hospital health and safety committee and other relevant committees.

13.2 Service Provision

Standard 36: Patients are systematically registered, receive radiological services in line with written requests and have their x-rays reported promptly and accurately.

Indicator 348: Patients are registered, assigned a registration number and given special instructions in a systematic way.

Indicator 349: Request Forms are of a standard format and contain:

- Patient's name
- Identification number
- Date of birth (if not available, age)
- Examination requested
- Previous examinations
- Clinical diagnosis/indications/relevant history
- Information relating to the pregnancy rule in women of childbearing age
- Identity of requesting physician
- History of allergy
- For medico legal cases mark of identification of the patient and name of police official bringing the patient

Indicator 350: Diagnostic imaging is performed only upon a signed written request from a qualified medical practitioner.

Indicator 351: Arrangements are in place for dealing with out of hours or emergency requests.

Indicator 352: A written policy agreed with the radiologist defines the terms under which pregnant women may be subjected to radiological examination

Indicator 353: All films are read by a radiologist and the written radiologists' reports are received by the hospital within a defined time after examination.

Indicator 354: Required reporting times are based on the urgency of the situation, e.g. films or scans for emergency patients are reported within one hour and routine reports are reported within 24 hours.

Indicator 355: If a radiologist is unable to report on the film in a timely manner a written, signed interpretation of the radiograph is made by an appropriate clinician whose skills are relevant to the area radiographed, E.g., chest radiography by a chest physician or bone/joint radiography by an orthopaedic surgeon.

Indicator 356: Critical or unexpected findings are discussed with the referring doctor.

Indicator 357: Radiology reports or copies of the reports are placed in patients' medical files in the wards.

13.3 Safety

Standard 37: Radiological services are provided in accordance with current radiation rules and regulations, risks are minimised and the safety of patients and staff are protected.

Indicator 358: Signs warning women of childbearing age of the dangers of radiation in pregnancy are prominently displayed.

Indicator 359: All examinations using ionising radiation are performed by suitably trained personnel.

Indicator 360: Staff provides services in accordance with current ionising radiation regulations and statutory requirements.

Indicator 361: Emergency drugs and equipment including all resuscitation equipment are functioning, are readily accessible and are monitored.

Indicator 362: All staff working in radiology services attend update courses on resuscitation, current radiology trends and evidence-based practice.

Indicator 363: Protective clothing is provided and used where biohazards or radiographic equipment is present.

Indicator 364: The radiologist in charge is responsible for ensuring that compliance with national guidelines is monitored:

- Staff working with radiological equipment wear radiation monitoring devices
- These devices are assessed and maintained in accordance with statutory regulations
- Records of these tests are kept for the working lifetime of staff employed by the service

13.4 Facilities and Equipment

Standard 38: Facilities and equipment are provided and maintained to maximise patient comfort and safety.

Indicator 365: A separate registration area for patients is provided and a toilet with washing facilities for special investigations is located adjacent to the examination room.

Indicator 366: A separate waiting area for males and females with adequate seating and separate male and female toilets and washing facilities are provided for the comfort of patients waiting for services and for their families.

Indicator 367: The appropriate hospital advisory committee (or its equivalent) with representation of radiology staff is consulted before any diagnostic equipment is installed.

Indicator 368: All equipment is subject to tests on installation to ensure the equipment meets with contract specifications and confirms mechanical, electrical and radiation safety.

Indicator 369: Records of these tests are kept in the department for reference.

Indicator 370: The workload of each piece of diagnostic equipment and staff is defined and used for determining the resources needed for the department.

Indicator 371: Radiology equipment is stable, functioning and installed only in properly lead protected rooms.

Indicator 373: A planned preventative maintenance programme is followed to keep equipment in sound working order.

Indicator 374: The radiation safety of essential equipment is regularly monitored and reported.

PHARMACY SERVICES

14.1 Management

Standard 39: The pharmaceutical service is managed and organised to provide efficient and effective pharmaceutical services through rational use of drugs within the hospital.

Indicator 375: The pharmaceutical service is managed by a qualified, graduate and registered pharmacist.

Indicator 376: A suitably qualified deputy with specified duties and responsibilities is designated in the absence of the pharmacist.

Indicator 377: Sufficient and appropriately qualified staff is available to fulfil the job descriptions and the defined services.

Indicator 378: A qualified pharmacist or designated deputy is on duty or on call outside normal working hours to provide a pharmaceutical service.

Indicator 379: Staff follows written policies and procedures for ordering and purchasing, controlling, storing, dispensing and disposing of all medicines within the hospital in compliance with legal requirements.

Indicator 380: The department monitors the quality of its services using an internal quality control program and staffs participate in the Hospital's quality improvement system.

Indicator 381: The pharmacy service provides a regular prescription monitoring service, locally, to ensure the safe, effective and economic use of medicines. This includes:

- Identifying inappropriate medication
- Monitoring adverse reactions
- Monitoring dispensing errors
- Checking adequacy of labelling of drugs and information on package inserts
- Physical examination of drugs to assess their quality and expiry dates
- A mechanism to encourage prescription of cost-effective and economical drugs

Indicator 382: The pharmacist is a member of the purchase committee.

14.2 Selection, Ordering and Purchasing of Medication

Standard 40: Selection and procurement of medication is appropriate to the scope of service, patient needs, and cost-effectiveness.

Indicator 383: The hospital formulary is prepared in a collaborative process considering patient needs, services provided in the hospital, cost-effectiveness and evidence-based criteria.

Indicator 384: The hospital formulary is in accordance with existing provincial/national guidelines, e.g. National Essential Drugs List (NEDL).

Indicator 385: Written policies and procedures exist and are implemented for the following processes:

- Tendering
- Evaluation of tenders
- Selection
- Ordering
- Reception and physical examination of delivered drugs

Indicator 386: Evaluation of tenders and selection of the provider occurs through a transparent process based on specific criteria including quality and cost.

Indicator: 387: The quality, quantity and expiry date of purchased medicines are checked upon receipt.

Indicator 388: Samples of delivered drugs sent to the Drugs Testing Laboratory for quality check.

Indicator 389: The list of medications available in the hospital pharmacy is available to all units

Indicator 390: A process exists to obtain required medications not stocked or normally available in the hospital pharmacy.

14.3 Storage and Stock Management

Standard 41: Stock is stored and managed to ensure that medications are current, kept safe and are continuously available to meet the needs of clinical staff and patients.

Indicator 391: Medicines are stored on shelves enabling:

- Protection from the adverse effects of light, dampness and temperature extremes
- Freedom from vermin and insects
- Adequate ventilation

Indicator 392: Medicines for emergency use are stored in sealed tamper evident containers in all patient areas.

Indicator 393: Adequate and secure storage facilities provided include:

- A suitable cupboard or container for the storage of flammable and/or hazardous material
- A functioning pharmacy refrigerator

Indicator 394: Controlled drugs are stored separately in a cupboard, securely fixed to the wall or floor, to comply with drugs regulations.

Indicator 395: Stocks of controlled medicines are ordered by an authorized

Indicator 396: A formal stock control system is used by the department and for the hospital.

Indicator 397: There is a stock list with agreed par levels for all wards and departments.

Indicator 398: Medicines required in an emergency are available and replaced promptly after use.

Indicator 399: All expired or recalled medicines, including unwanted medicines returned by patients and unused controlled medicines, are safely disposed of in accordance with a written procedure.

Indicator 400: A formal, written procedure is followed to action hazard warnings and medicine recalls.

Indicator 401: A formal, written procedure is followed for retention of order forms, copy of delivery notes, stores receipt, and issue vouchers, and book of records (controlled drugs book/prescription drugs book) on the premises as provided for in the relevant laws.

14.4 Prescribing, Administration and Dispensing of Medicines

Standard 42: Prescribing, dispensing and administration of medications are safe, efficient and effective and promote best possible treatment outcome.

Indicator 402: A system is in place to ensure that:

- Prescriptions are only issued by authorized prescribers
- Administration of medicine is done by, or under the supervision of, competent health personnel

Indicator 402: All prescriptions are legible and duly signed by a doctor, including the following:

- Name and additional identifier
- Age, Sex and weight (where applicable)
- Diagnosis
- Name of Medication, dose, route, frequency and duration
- Clear identification of prescriber

Indicator 403: Staff follows a written policy for the verbal ordering of medicines in emergencies which has been agreed by medical, nursing and pharmacy staff.

Indicator 404: Medicines are dispensed by, or under the supervision of, a pharmacist in accordance with a written prescription from a qualified registered medical practitioner.

Indicator 405: The patient is provided with written and verbal information on the prescribed medicine including:

- The costs
- The potential benefits and adverse effects
- How to use medicine safely and properly
- Risks of ignoring instructions

Indicator 406: There is an approved hospital prescription/medication chart on which all medicines for an individual patient are prescribed and their administration recorded.

Indicator 407: A pharmacy registers records:

- Patient name and registration number
- Date
- Diagnosis
- Medicine dispensed
- Name of the pharmacist

Indicator 408: Staff follows written, dated and signed procedures on the following:

- What medicines may be administered without a prescription and under what circumstances
- Self-medication
- Use of antibiotics
- Administration of IV drugs, narcotics, psychotropic substances and cytotoxic
- Obtaining medicines after hours from hospital pharmacy
- Obtaining medicines that are not available within the hospital pharmacy
- Dealing with patients' own medicines.

Indicator 409: Medical practitioners follow policies for antibiotic prescribing which include:

- Restricting the use of broad-spectrum agents to minimise the development of resistant viruses and bacteria
- Using prophylactic antibiotics only where their efficacy has been established

Indicator 410: Current editions of reference books, including pharmacopoeia, the copy of the National Essential Drugs List (NEDL)/hospital own formulary, standard treatment guidelines and other information booklets are available.

14.5 Facilities

Standard 43: *Facilities and equipment are safe and adequate for the purpose and the number of patients attending the pharmacy.*

Indicator 411: All doors, windows and hatches within the pharmacy can be locked.

Indicator 412: There is a designated area for:

- The receipt and unpacking of goods in wards
- Segregation of expired and recalled drugs
- Dispensing of medicines

Indicator 413: The pharmacy has an administrative area

Indicator 414: There is a specific drug information/reference area for use by hospital staff.

Indicator 415: There is a designated waiting area for patients.

Indicator 416: A box or trolley containing those medicines which may be urgently required in the event of a cardiac arrest is available.

Indicator 417: Where a medicine trolley is used to store medicines, it is lockable and secured when not in use.

Indicator 418: Lockable medicine refrigerators with maximum and minimum thermometers are provided for medicines requiring cool storage. They are used solely for this purpose.

Indicator 419: Temperatures are regularly monitored and recorded and action is taken where a temperature varies from an acceptable range.

INFECTION CONTROL, HYGIENE AND WASTE MANAGEMENT

15 INFECTION CONTROL

Standard 44: *The organisation designs and implements a coordinated program to reduce the risks of nosocomial infections in patients, visitors/attendants, contractors and staff.*

Indicator 420: The hospital establishes an infection control program designed to prevent or reduce the incidence of nosocomial infection, based on current scientific knowledge and accepted practice guidelines and developed and monitored with multidisciplinary involvement.

Indicator 421: The infection control program includes all areas of the hospital and describes the scope, objectives, annual activities, surveillance methods, resources and processes

associated with infection risks, including respiratory tract, urinary tract and surgical wound infections, are identified and included in the infection control program.

Indicator 422: Responsibility for coordinating the infection control program is assigned to an infection control committee with representatives of all relevant disciplines and departments including medical, nursing, microbiology/pathology, kitchen and laundry staff.

Indicator 423: The infection control committee has clear written Terms of Reference that include the following responsibilities:

- Coordination of infection control activities
- Development, implementation and monitoring of the infection control program
- Approval of infection control policies and procedures
- Approval of surveillance activities
- Reviewing and analysing infection control data
- Following up identified infection control issues with relevant action, including education
- Evaluating the effectiveness of actions taken

Indicator 424: The infection control committee is linked with Waste Management Control

Indicator 425: The infection control program is adequately resourced and staffed with appropriately qualified health professionals (nurses and/or doctors) with responsibilities defined in a job description for:

- Implementing the infection control program in consultation with staff and patients
- Implementing policies
- Educating staff
- Providing infection control advice
- Developing and implementing methods of surveillance, including reviewing infection control practices
- Providing reports and making recommendations to the infection control committee

Indicator 426: Infection risks, rates and trends are tracked, analyzed and reported.

Indicator 427: Surveillance of multiple resistant organisms and organisms associated with antimicrobial use is conducted as part of the infection control program.

Indicator 428: There is evidence of regular infection control audit.

Indicator 429: Cultures are obtained regularly from designated sites in the hospital with significant infection risks and action taken to minimise any identified infection.

Indicator 430: Relevant support staff are appropriately inducted and trained in basic aspects of infection control relevant to their work including:

- Basic concept of microbes
- Proper hand washing
- Segregation of waste and hazards associated with waste

Indicator 431: Staff are appropriately inducted and trained in all aspects of infection control relevant to their work, including proper hand washing.

Indicator 432: Written and dated organisation wide infection control and waste management policies and procedures are used by staff. Procedures include, but are not limited to, the following topics:

- Use of standard precautions including hand washing techniques
- Sterilisation and decontamination of equipment
- Food hygiene
- Laundry and linen management
- Identification and management of organisation-acquired infections
- Management of outbreaks of infection
- High risk and communicable diseases
- Operation of the mortuary, where applicable
- Collection, storage and disposal of infectious waste, body fluids, tissues, blood and blood products
- Disposal of sharps and needles
- Cleaning of all hospital surfaces, supplies and equipment, E.g., floor, walls, ceilings, beds and basins
- Management and cleaning of spillage
- Vaccination of staff

Indicator 433: Gloves, gowns, masks, soap and disinfectants are available and correctly used in situations where there is a risk of infection.

Indicator 434: Procedures are used for the isolation of patients specific to the reason for isolation.

Indicator 435: There are procedures in place for identifying and treating patients admitted with MRSA.

16 STERILE SUPPLIES

Standard 45: Equipment and supplies are sterilised to minimise risk of infection in patients and staff.

Indicator 436: The Infection Control Committee oversees the provision of sterile supplies.

Indicator 437: There is a defined department or area for sterilisation which physically separates the functions of cleaning, processing and sterile storage and distribution.

Indicator 438: In all areas where instruments are cleaned there is airflow to prevent cross-contamination and to keep material within the area.

Indicator 439: There is at least one functioning steriliser with a drying cycle

Indicator 440: The responsibilities of relevant staff members managing the provision of sterile supplies are clearly defined and specified in writing.

Indicator 441: Staff responsible for the decontamination, inspection, function testing, assembly and packaging, terminal processing, storage and distribution of supplies are adequately trained.

Indicator 442: Current written policies and procedures covering the functions of sterilisation, including the following, are available with documented evidence of routine compliance:

- Receiving, cleaning and disinfection of used items
- Preparation and processing of sterile packs
- Storage of sterile supplies and expiry dates
- Decontamination of instruments prior to sending for repair, maintenance or servicing
- Handling of instruments following an infected case
- Handling of equipment identified as "bio-hazard"
- Product labelling, batch numbering and identification
- Restricted personnel access to the clean production area
- Cleaning procedures, manual methods
- Housekeeping procedures
- Infestation control
- Personal hygiene
- Microbiological and environmental monitoring
- Criteria for testing and replacing air filters
- Recall procedures

Indicator 443: Sterilisation procedures are based on existing provincial or national/international guidelines.

Indicator 444: The sterilisation status of sterilised goods is assessed by the use of temperature sensitive tapes, using indicators as recommended by the manufacturer.

Indicator 445: Reports of quality control tests on sterilisers are reported to the infection control committee at least quarterly.

Indicator 446: The person using sterilised equipment checks that the decontamination of the equipment has been done before using that equipment.

Indicator 447: Stock levels of sterilised goods are checked by an ongoing inventory management process.

Indicator 448: Records are available for:

- Acceptance of load procedures
- Plant history records
- Sterile goods issued to wards/departments
- Sterilisers and autoclaves (history and servicing)
- Servicing and calibration

Indicator 449: All trays/packs/containers are stored in conditions that preserve the integrity of their packaging to prevent damage and/or contamination.

Indicator 450: All packs are marked with:

- Name of the article
- Contents of the pack
- Initials of the person who packed it
- Date and initials of the person who sterilized it

Indicator 451: Each tray, container or pack of instruments has a completed checklist which is used at the time of packing, at the time of use in the OT, and at the time of return of the instruments for re-sterilization.

17 CLEANLINESS AND SANITATION

Standard 46: All hospital facilities, equipment and supplies are kept clean and safe for patients, visitors/attendants and staff.

Indicator 452: Staff follows written policies and procedures and schedules for:

- Disinfection and cleaning of all equipment, furniture, floors, walls, storage areas and other surfaces and areas
- Cleaning of specialized areas, e.g. OT, Labour Room, Emergency Ward, Dressing Room, Laboratory and ICU

Indicator 453: Hospital premises are free from litter and other refuse.

Indicator 454: Sufficient covered, clean dustbins are provided for patients, visitors/attendants and staff and the dustbins are emptied on a regular basis.

Indicator 455: Equipment, floors and walls are free from bodily fluids, dust and grit and the masonry is intact.

Indicator 456: Cleaners are trained and provided with sufficient appropriate equipment and cleaning material and work according to cleanliness and sanitation policies and procedures.

Indicator 457: Laundry staff is trained and work according to linen and laundry policies and procedures including but not restricted to the following:

- Collection of sluiced and dirty linen from the individual departments
- Transportation with clear separation of clean and dirty laundry
- Separate storage of clean and dirty linen
- Sorting of linen into soiled, infected and foul linen and washing processes and washing processes for this linen
- Removal of blood stains/sluicing
- Disinfection/autoclaving
- Washing / hydro extraction
- Drying
- Repairs of linen if required
- Pressing
- Distribution to individual departments
- Storage in individual departments
- Record keeping for receipt and distribution of clean linen

Indicator 458: Kitchen staff and/or those handling foods are trained and work according to policies and procedures including but not limited to the following:

- Cleaning of all areas and surfaces on which food is stored and prepared, E.g., all preparation surfaces are cleaned and dried between uses for different activities
- Food storage, e.g. all food is stored separately from non-foods, cooked food is stored separately from uncooked/raw food and the covering and labelling of food
- Use and cleaning of equipment for food preparation, handling and transport, e.g. separate cutting boards are used for raw and cooked foods
- Testing and monitoring of safe temperatures for cooked food
- Testing and monitoring of refrigerator temperatures for safe food storage

Indicator 459: Access to the kitchen is restricted.

Indicator 460: All staff handling food has health checks prior to appointment and at regular intervals during their employment and records are kept.

Indicator 461: A written Dress Code for those working in the kitchen is enforced including wearing of head cover for hair, clean uniforms and appropriate footwear.

Indicator 462: The kitchen and food stores have proper ventilation.

Indicator 463: All windows in food preparation and storage areas have suitable fly screens and insectocutors (ultra-violet electric flying insect removers) are present in designated problem areas.

Indicator 464: Kitchen walls are made of material

Indicator 465: Kitchen waste is put in covered secure containers and removed immediately from places where food is prepared pending disposal.

Indicator 466: Kitchens are arranged to be away from waste storage, ward areas, laboratories and other areas of risk of contamination and infection.

18 WASTE MANAGEMENT

Standard 47: *Clinical and other infectious or injurious waste is handled, stored and disposed of to minimise harm and risk of infection/injury to patients, visitors, contractors, staff and the community.*

Indicator 467: The hospital has a written waste disposal plan, specifying procedures, responsibilities, timetable for waste collection and necessary equipment such as bins and bags.

Indicator 468: The waste disposal plan includes written guidelines for the regulation, identification, containment and storage, transport, treatment and subsequent disposal of different categories of infectious waste in accordance with the relevant national/provincial laws, including if appropriate:

- Pathology waste
- Cytotoxic and chemical liquid waste
- Heavy metals, radio-active or any other form of high-risk waste

Indicator 469: Infection control and waste management personnel use the

Indicator 470: Suitably qualified and experienced person(s) with designated responsibility lead the development and regular updating of plans and policies and procedures for waste management and the process is overseen by the Infection Control Committee and infection control personnel.

Indicator 471: Responsibilities for waste management are defined in all job descriptions.

Indicator 472: Staff is trained in and uses procedures for different types of waste:

- Collection
- Segregation at source
- Storage
- Transportation
- Disposal

Indicator 473: All staff who works in areas where infectious waste is handled is trained on hazards of waste, management of waste and infection control.

Indicator 474: Incineration facilities, where provided, are certified as conforming to health and safety and environmental health requirements by the Local Authority.

Indicator 475: If contractors are used for the removal and incineration of clinical waste, a written contractual agreement and consignment procedure is used which includes identification of the origin, contents and quantity of the waste.

Indicator 476: All waste is protected from theft, vandalism or scavenging by persons or animals.

Indicator 477: A clear guide for waste segregation and storage is visibly posted in area(s) where this waste is generated and includes waste segregation in clearly labelled coded bins in accordance with the relevant national/provincial laws.

Indicator 478: Prior to collection and disposal, waste is kept in a suitable location which does not cause a hazard.

Indicator 479: Records on the quantity of waste generation in each category of waste are maintained, analyzed and the resulting information is used for statistical and quality improvement activities by the Hospital.

SAFE AND APPROPRIATE ENVIRONMENT

19 HEALTH AND SAFETY

Standard 48: Promotion of health and safety and the avoidance of risk to human life as well as to the property of the Hospital are integrated within the organisation and among all levels of staff.

Indicator 480: The responsibility for health and safety of hospital management and other relevant staff is included in their job descriptions and performance reviews.

Indicator 481: A Health and Safety Committee meets on a regular basis, includes representatives of management and staff from different departments and enables two-way communication between management and employees on issues of interest and concern related to health and safety.

Indicator 482: Health and Safety Committee meetings follow a set agenda that includes follow-up from the last meeting, minutes of each meeting are kept and the agendas and minutes are readily available to all staff.

Indicator 483: The Health and Safety Committee participates in the development of the Risk Management Plan.

Indicator 484: All new employees are trained in Health and Safety procedures relevant to their duties within one month of taking up their post.

Indicator 485: All staff attends continuing training for health and safety and records are kept of the trainings

Indicator 486: Each department uses a systematic process to:

- Regularly identify and record actual and potential hazards in a hazard register (at least annually)
- Assess identified hazards to determine which are significant
- Eliminate, isolate or minimise the impact of the significant hazards

Indicator 487: Staff reviews significant hazards that have been isolated or minimised in accordance with a set timetable appropriate for the identified hazards.

Indicator 488: All emergency telephone numbers concerned with Health and Safety are displayed prominently.

Indicator 489: Health and Safety policies and procedures are followed by staff and include:

- Contamination incidents
- Sharps and needle-stick injuries
- Drug dependence
- HIV/AIDS
- Hepatitis B and C
- Lifting and manual handling of patients and equipment
- Basic life support

Indicator 490: Organisation wide health and safety policies and procedures contain comprehensive information, instruction and safety protocols for:

- Control of waterborne diseases
- Storing and handling of inflammable liquid
- Personal protective equipment and clothing
- Review of pressure vessels and systems
- Body fluid spillage
- First aid procedures at work
- Violence and aggression towards staff
- Outbreak and prevention of fire
- Other internal accidental events such as explosion
- Safe use of electrical equipment
- Safe disposal of clinical waste
- Safe handling of gas cylinders
- Safety precautions necessary when storing, handling and using liquefied gases, E.g., nitrogen and oxygen
- Control and prevention of spillage of hazardous substances, like mercury and glutaraldehyde
- Cytotoxic drugs
- introduction of new technology

Indicator 491: Current health and safety notices, including hazard notices, and key extracts from the Health and Safety manual are prominently displayed in relevant areas and brought to the attention of staff.

Indicator 492: There is a procedure for ensuring that all contractors are provided with relevant information regarding health and safety issues within the hospital.

Indicator 493: A written policy and procedure on pest control including measures to prevent, detect and remove pests is available and implemented.

Indicator 494: Security measures are taken in accordance with written policies and procedures to protect:

- Staff working alone or in isolation
- Patients, visitors and staff from assault and loss of property during the day and at night
- Drugs from being taken illegally
- Hospital's facilities and assets from damage and loss

Indicator 495: A procedure ensures that all hospital keys are available at all times to the relevant staff on duty.

Indicator 496: An internal communication system connecting all units of the hospital enables a continuous flow of communication and immediate reporting of any incident.

20 FIRE SAFETY AND EMERGENCY PREPAREDNESS

Standard 49: *The organisation minimises the risks of fire and protects patients, visitors and staff in case of fire and is prepared for disasters and emergencies.*

Indicator 497: A fire safety plan exists including prevention/risk reduction, early detection, suppression, abatement, and safe exit from fire.

Indicator 498: The hospital building, e.g. doors, exits and corridors, is constructed in a way to minimise the risk of fire and conform to fire safety rules, including:

- Doorways, corridors, ramps and stairways being wide enough for the evacuation of non-ambulatory patients
- Fire and smoke doors being able to be opened and closed manually or by an electric release system
- Doors to patient rooms and exit doors not being locked from the inside

Indicator 499: Access and exit ways are kept free of obstruction at all times to allow for safe evacuation in a fire or other emergency.

Indicator 500: An annual inspection of fire safety in the Hospital results in identification of fire risks and strategies to minimise the risks and prevent fire.

Indicator 501: A person responsible for Hospital Safety carries out and records regular tests of alarm systems, fire extinguishers and other facilities and equipment for fire prevention and control.

Indicator 502: Action is taken to address any recommendations made during inspections and testing.

Indicator 503: All hospitals have an alarm system

Indicator 504: Pictograms indicating fire exits and escape routes are properly illuminated, clearly visible, unobstructed and are displayed at appropriate locations.

Indicator 505: Potentially explosive, flammable or highly combustible materials are clearly identified, securely stored and storage areas are clearly signed.

Indicator 506: Areas where smoking is dangerous, restricted and allowed are clearly signed and monitored.

Indicator 507: Hydrants are provided in the hospital.

Indicator 508: Staff is trained at least annually in fire safety and other emergency procedures.

Indicator 509: Fire procedures and evacuations are tested and disaster and emergency drills are practiced regularly.

Indicator 510: The Hospital develops a disaster plan with all departments/services.
.and is reviewed and revised at least every two years.

Indicator 511: The plan outlines individual responsibilities, linkages with external institutions, resources required in the case of a disaster and individuals within the hospital who must be informed in the case of a disaster.

Indicator 512: Rehearsals of the disaster plan are carried out in association with the emergency services and local authorities.

21 SAFE AND APPROPRIATE EQUIPMENT

Standard 50: There are clear and documented responsibilities, policies and procedures for procurement, use, maintenance, repair and disposal of equipment to minimise the potential for harm.

Indicator 513: A team with clearly defined roles meets as required and includes those in charge of the hospital, nursing, maintenance and stores and other relevant departmental representatives.

Indicator 514: Basic responsibilities of the team include:

- Assessment of need for new equipment
- Consultation with the requesting department on their requirements and specifications for the equipment
- Procurement of equipment
- Assessment of utilisation of equipment
- Condemnation of equipment as appropriate
- Conducting regular equipment audits

Indicator 515: The procurement policy for equipment and supplies includes the criteria that equipment and supplies purchased are consistent in type and brand with others in the Hospital to facilitate maintenance and repair.

Indicator 516: Placement of supply orders of equipment is done in accordance with the hospital rules or GFR (Government Financial Rules) in case of public hospitals and a copy of supply orders for equipment is kept in the Hospital records.

Indicator 517: A written procedure is used for receiving ordered equipment and includes at least the following activities:

- At time of delivery the equipment is inspected as per specifications given in the supply order by the equipment committee/user department.
- On satisfactory receipt, installation and commissioning of the equipment a certificate to that effect is given by the equipment committee/user department.
- Payment of the supplier is only made on production of such a certificate
- Originals or a copy of the service contract and operational manual are kept in the maintenance department or other designated department

Indicator 518: Equipment is certified as conforming to health and safety requirements and regulations.

Indicator 519: For costly equipment annual maintenance contracts are made including:

- Regular service and maintenance for at least five years after the warranty period
- Warranty with cost-free provision of spares
- Continuous supply of consumables
- Training of staff to handle the equipment
- Reliable and prompt after-sale service
- Penalty clause if any delay occurs due to the negligence of the supplier

Indicator 520: The suppliers contact details and emergency telephone number is available.

Indicator 521: Staff is allowed to operate equipment or machinery are appropriately trained

Indicator 522: Records of equipment are kept including procurement, equipment defects and failures, maintenance, repair and disposal.

Indicator 523: A maintenance workshop with qualified and experienced persons having basic knowledge of physics and electronics has defined responsibilities for maintenance and repair of smaller equipment.

Indicator 524: The equipment maintenance staff is trained by the suppliers in the following issues:

- Use and practice of equipment including proper handling of the equipment
- Preventive maintenance and trouble shooting
- Following the instruction manual in day-to-day use of the equipment
- Common and recurrent causes of break-down
- Common spare parts responsible for frequent break-downs
- Inspection and routine maintenance
- Calibration
- Testing and safety guidelines
- Technology up-gradation
- Documentation of procedures for maintenance (SOPs)

Indicator 525: A list of all electrical equipment that requires routine testing is used and a record of maintenance and testing of this equipment is kept for three years, e.g. generator, emergency lighting.

Indicator 526: Regular and routine checks of equipment (equipment audit) are carried out in accordance with the operational manual, maintenance contract and/or a history sheet of the equipment by the Store in-charge.

Indicator 527: Safeguards for electronic equipment are used such as:

- Voltage stabilizer
- Automatic switch over for emergency (generator)

Indicator 528: A logbook for all critical equipment is kept and a record of incidence of defects and failures in equipment is maintained

Indicator 529: There is a form known to all staff and used to request equipment repairs and defects

Indicator 530: An adequate and sufficiently large room and supplies are available for maintenance and minor repairs. Supplies include but are not limited to:

- A bank of spare parts
- Toolkit

Indicator 531: A list of maintenance/backlog items is kept and reviewed regularly.

Indicator 532: Written procedures exist for

- Requests for repair from outside agencies if equipment cannot be repaired in-house
- Condemnation and disposal of obsolete equipment

Indicator 533: A list of approved external repair workshops is kept and regularly updated

Indicator 534: All requests for repair, work carried out and response time to reported defects is monitored and documented.

Indicator 535: The procedure for condemnation and disposal of obsolete equipment includes criteria for defining 'condemned' and 'obsolete' equipment, such as:

- Non-functional and beyond economical repair
- Non-functional and obsolete
- Functional but obsolete
- Functional but hazardous
- Functional but no-longer required

Indicator 536: An annual budget is provided for the maintenance and scheduled replacement of equipment.

22 SAFE AND APPROPRIATE FACILITIES

Standard 51: The Hospital's physical environment contributes to the safety and well-being of patients, staff and visitors.

Indicator 537: The hospital complies with relevant laws and regulations related to design and layout of the facility and inspection requirements are fulfilled.

Indicator 538: Corridors, storage areas, passageways and stairways are well lit.

Indicator 539: Access ways and exits are unobstructed at all times.

Indicator 540: Signage allows safe passage through the hospital and exit from the facility in case of an emergency, disaster or fire.

Indicator 541: The environment in all patient areas is clean, well lit, ventilated with adjustable controls for lighting and heating, and decor is in good repair.

Indicator 542: Floor surfaces are non-slip and even.

Indicator 543: Facilities and equipment for the safety and comfort of patients and visitors are available and functioning and include:

- Refreshment facilities and canteen
- Quiet rooms for consultations
- A public telephone

- Baby changing/feeding facilities
- Wheel chair / stretcher
- Defined and understandable signage system
- Adequate Chairs
- Cooling device, fans
- Separate queues for male and females wherever required
- Safe drinking water facilities
- Sheltered outside areas with planting and greenery

Indicator 544: A functional call bell system is available for use in private and isolated wards (single occupancy rooms), within easy reach of the patient.

Indicator 545: Each nursing area has a clean storage and preparation space and is separate from soiled materials, domestic equipment and sluice areas.

Indicator 546: Separate male and female toilets and bathrooms are available and adequate for the number of patients in the ward or department (at least one toilet for every twelve patients). The toilets and bathrooms:

- Are kept clean
- Are lockable by the patient from the inside but un-lockable from the outside
- Have doors that open outwards
- Ensure privacy at all times
- Have a non-slip base
- Have grab rails positioned on either side of the toilet
- Have an alarm-call within easy reach of the bath and toilet

Indicator 547: Shower facilities are available, with warm water for winter months.

Indicator 548: Separate male and female functioning, clean toilets are available for use by visitors/attendants.

Indicator 549: Bed tables are available.

Indicator 550: Potable water and electrical power are available 24 hours a day, seven days a week.

Indicator 551: Alternate sources of water and power for heat and lighting in case of breakdown of the systems are identified, functioning and regularly tested. Priority areas such as ICU and Operating Theatres are identified.

Indicator 552: Electrical, water, ventilation, medical gas, and other key systems are regularly inspected, maintained and improved, if necessary.

SCHEDULE-II

Foreword

This Pakistan Standard was adopted by the Pakistan Standards and Quality Control Authority; Standards Development Centre on 07-12-2013 after the draft finalized by the Technical Committee on Primary Healthcare Facilities had been approved the National Standards Committee on Healthcare.

Pakistan Standards and Quality Control Authority (PSQCA), under the Ministry of Science and Technology is the national standardization body and performing its duties and functions in accordance with PSQCA Act No. VI of 1996. PSQCA is established to advise the Government on standardization policies, program and activities to promote industrial efficiency and development, as well as for consumer protection. The main function of this Authority is to foster and promote standards and conformity assessment as a means of advancing the national economy, promoting industrial efficiency and development, ensuring the health and safety of the public, protecting the consumers, facilitating domestic and international trade and furthering international co-operation in relation to standards and conformity assessment.

PSQCA establishes Pakistan Standards as per mandate given in sub-section (xvi) of section 8 of PSQCA Act No. VI of 1996 i.e. framing and publishing, amending, revising or withdrawal of the Pakistan standards in relation to any article, product, process and in accordance with Pakistan Standards Rule, 2008. For further information on Pakistan standard development, please visit PSQCA website www.psqca.com.pk.

The formulation and or adoption of Pakistan Standards is carried out in Technical Committees and endorsed by National Standards Committee which include PSQCA experts, intellectuals from related scientific institutions, technical experts from relevant production units and consumers. Effort is made to make sure Pakistan Standards safeguard national interests, public tendencies, and the views of all stakeholders such as producers, consumers, businessmen, specialized centers as well as government organizations are satisfied.

This is the first concentrated effort made so far to prepare comprehensive standards involving stakeholders from all provinces and regional areas for the healthcare services which are applicable in national context.

INTRODUCTION

There is a felt need for quality improvement and management in health care delivery system so as to make the same more effective, economical and accountable. Isolated activities have been made but this is the first concentrated effort made so far to prepare comprehensive standards involving stakeholders from all provinces and regional areas for the healthcare services which are applicable in national context.

This Pakistan Standard provides a framework to assess the quality of care provided in public and private primary health facilities and to improve quality in a structured manner. In this way, they are a useful management tool for individual primary healthcare facilities to identify their strengths, gaps and areas for improvement and provide one mechanism for the Government to identify priority areas for overall improvements in the healthcare delivery system.

This Pakistan Standard on primary healthcare facilities is based on Khyber Pakhtunkhwa (KP) Standards for Primary Health Care developed and field tested by the Department of Health, Government of KP. The KP Standards for Primary Health Care Facilities are based on PHC Standards developed in the African context. To adjust these standards to the needs and the reality of KP, they were tested in a small number of public and private primary facilities in KP. After the initial testing, a first revised draft was prepared and discussed with experts drawn from, private, public and NGO, Medical Associations, basic health units, rural health centers district and teaching hospitals, and other hospital support service areas by the Department of Health to ensure that this standards were relevant, important, understandable, measurable and achievable in Pakistani context.

The standards and their criteria have been specifically developed for the Pakistan primary healthcare setting by the committee. Each section consists of “**standards**” and “**measurable criteria**”. Whereas “standards” are broad statements of the expected level of performance, the “measurable criteria” make the standards operational and provide details on structures and processes necessary to ensure high quality of care.

IHRA Standards for Primary Healthcare Facilities

1. SCOPE

This Pakistan Standards prescribe the service management and service provision standards for primary healthcare facilities. Primary health care provides immediate and

the first point of consultation and often continuing care for all patients. The services provided are mainly preventive, outpatient and basic inpatient. These facilities are coordinated with higher levels of the health system (secondary & tertiary care) that can provide more specialized care when needed.

2. NORMATIVE REFERENCES

- PS 5255:2013 Pakistan Standard on Healthcare – Terms and Definitions on Healthcare

3. TERMS AND DEFINITIONS, AND ABBREVIATIONS

For terms and definitions, please see PS 5255:2013 (Pakistan Standard on Healthcare – Terms and Definitions on Healthcare).

4. REQUIREMENTS FOR SERVICE MANAGEMENT:

4.1 Primary Care Management Committee

A Primary Care Management Committee plans and manages its resources, supports the Service's processes and communicates decisions and information to relevant persons and organizations.

- a. The Primary Care Management Committee includes representatives from local government, staff and users.
- b. Clients/Users who are members of the committee are provided with information to enable them to contribute to the decisions of the health committee.
- c. All members of the committee are oriented and trained in healthcare system, processes for running meetings and in basic management skills.
- d. The committee meets regularly according to a set agenda that includes follow-up from the last meeting.
- e. Minutes of meetings are kept for five years and are available at the facility.
- f. An annual planning process results in an annual plan which is implemented and reviewed on a regular basis.
- g. The annual plan includes goals, planned actions, staffing and financial and physical resources to implement the planned actions.

- h. Monthly HMIS Reports are submitted to EDO Health and include progress against the annual plan, identify problems and make recommendations.

4.2 Client/Patient information

Client/Patient information is registered, coded, analysed and used as a mechanism for monitoring and planning

- a. Client/Patient registers are used, up to date, complete and accurate.
- b. Written information in the registers includes dates, client/patient characteristics (name, sex, age and address), diagnosis and treatment (dosage, times/day, no of days) and follow-up in line with operating procedures.
 - i. Registers used to document client/patient information include but are not limited to:
 - ii. Health card (mother and child) which is maintained and used as a mechanism for informing the client/patient about their care;
 - iii. Immunization card which is maintained and used as a mechanism for informing the client/patient about their care;
 - iv. Register of expectant mothers and deliveries which are maintained and analysed.
 - v. OPD register.
- c. A consistent disease coding system is used and analysed
- d. Analysis of the information is used by staff and results are fed back to the community.

4.3 Notifiable diseases

Notifiable diseases are reported promptly and appropriate action is taken to minimize the spread of the disease.

- a. A list of Notifiable diseases is available.
- b. Notifiable diseases are reported within a specified time period, but no longer than 24 hours.
- c. Procedures for managing Notifiable diseases are based on infection control principles, are used and roles and responsibilities are clearly defined.
- d. The 'Zero report' is completed and submitted weekly (for polio)

4.4 Provision of utility facilities and monitoring of equipment

The equipment and utilities are functional, meet the defined needs of planned services, and are properly maintained and used.

- a. Equipment is registered, maintained, repaired and disposed of according to an equipment maintenance and replacement schedule.
- b. The facility has functioning electricity and natural gas.
- c. A backup generator in working condition and the budget for its maintenance and for its fuel are available.
- d. A stretcher and at least two examination couches,
 - i. are available
 - ii. are clean with no visible dust, stains or blood, and
 - iii. are covered with a clean, uniform Macintosh or a plastic sheet.
- e. Each health worker providing curative services has the following functioning equipment:
 - i. Thermometer
 - ii. Stethoscope
 - iii. BP machine
 - iv. Screen for privacy
 - v. Gloves, masks, apron
 - vi. Torch.
- f. The following additional functioning equipment is available in the facility and ready to use:
 - i. Baby weighing scale, fetoscope, neonatal weighing scale, speculum
 - ii. Refrigerator, stools, lantern or alternate lighting source such as solar lamps or torch, equipment for boiling/ sterilizer, timing device, stainless steel bowls, kidney bowls, dressing drum, gloves, masks, aprons
 - iii. Adult weighing scale, nebuliser, suction machine, oxygen cylinder(?), x-ray viewer, suture set, needle safety box, resuscitation kit

- iv. ORS corner [including the following ORT equipment: water jug; 2 cups and 2 spoons]
 - v. ENT diagnostic set
 - vi. D&C set
- g. Additional equipment, based on the defined needs of the planned services, is available and functioning.

4.5 Water supply

There is a reliable, clean and safe supply of water from a protected water source.

- a. Running water (pipe) is available within the facility

OR there is a water tank within the facility

OR there is a protected water source within 200 metres of the facility: borehole, water tank or protected spring (with tubing of water for outflow, concrete slab, drainage and the spring is at least 33 meters away from latrines/toilets) and temporary storage containers, e.g. jerry cans or drum.

- b. A supply line and storage system that keeps water clean and free from contamination.

4.6 Waiting area

The waiting area is clean and protected.

- a. The waiting area protects clients/patients from the sun, rain and extremes of temperature.
- b. There are designated separate male and female waiting areas and toilets/latrines.
- c. The waiting area has chairs or other seating arrangements.
- d. The floor is swept or mopped and the area is clean of debris/ trash.
- e. The walls and ceiling are intact with no broken masonry and are free from dirt and stains.

4.7 Latrine facility

The facility has clean latrines or toilets.

- a. Latrines or toilets exist within the facility or facility compound.

- b. Staff and clients/patients have access to separate latrines or toilets which are clearly signed and are lockable from the inside.
- c. The client/patient latrine or toilet is not locked from the outside.
- d. The toilet bowl is clean and empty and/or the latrine slab is clean.
- e. Soap and water are available at the washing point near the toilet(s)/ latrine(s)

4.8 Work area

The facility compound is clean and uses a rubbish pit for disposal of refuse and medical waste.

- a. The compound is free from litter such as plastic bags, refuse and medical waste.
- b. There is a rubbish pit within the compound (possibly a garbage bin in urban settings)
- c. The pit (bin) is not overflowing and is properly used, i.e. rubbish is not disposed of anywhere else
- d. Medical waste is disposed of in a functional covered pit, e.g. not accessible for children and animals, within the compound.

4.9 Operability of the procedures and guidelines

The staffs work to written Operating Procedures for managing Primary Care services, written guidelines for management of clients/patients and written guidelines for common illnesses.

- a. Standard Operating Procedures are used for managing the facility, finances, equipment, cleaning procedures, and stocks, e.g. equipment maintenance
- b. National and Provincial Treatment Guidelines for the priority illnesses are available at the facility, form the basis of regular training for relevant staff and are followed in providing care to the patients/clients.
- c. Where National and Provincial Treatment Guidelines are not available, they are developed and used by the Primary Care service.
- d. Written guidelines for the management of clients/patients exist and are used, e.g. confidentiality, privacy, registration, recording and coding.

4.10 Availability of staff

Primary Care staff is available for service delivery during all official times.

- a. An updated roster is kept of who is on duty at what time.
- b. A qualified healthcare provider is available whenever the facility is open.

4.11 Staff

Staff are appointed, trained and evaluated in accordance with documented procedures, job descriptions and service needs.

- a. Staff appointments are made in line with the required qualifications and experience for the job and the job description.
- b. All staff are oriented to the Primary Care services and their specific positions through a documented induction programme.
- c. The induction programme includes:
 - i. The Service's mission, values, goals and relevant planned actions for the year
 - ii. Services provided
 - iii. Roles and responsibilities
 - iv. Relevant policies and procedures, including confidentiality
 - v. Use of equipment
 - vi. Safety
 - vii. Emergency preparedness
 - viii. Quality improvement.
- d. All staff has a copy of their job description that is kept current. The job description includes the responsibilities, accountabilities, tasks, performance measures and reporting relationships.
- e. All staff has a copy of their conditions of employment.
- f. Well-maintained and secure staff housing with all utilities is provided as per staff terms and conditions.
- g. Staff performance is evaluated annually with the staff member against their job description and agreed targets and is used to identify strengths, areas for improvement and training needs.
- h. Accurate and complete personnel records are kept at the facility.
- i. Staff receives on-going in-service training relevant to their job and the healthcare

service and in areas such as health and safety, quality improvement and client/patient rights.

- j. Documents guide the work of staff and cover staff appointments, performance evaluations, disciplinary procedures and terms and conditions of employment.

4.12 Health and safety

The health and safety of clients/patients, staff and visitors are protected.

- a. The Service is designed to allow service delivery to be safe, accessible and respect clients'/patients' needs for privacy.
- b. The Service is inspected annually by the Works and Services Department and declared safe.
- c. A current Safety Certificate has been issued and is displayed in the facility.
- d. Chemicals, drugs and equipment are stored safely.
- e. Risks and hazards are identified and eliminated, isolated or minimized as appropriate.
- f. Guidelines exist for major risks and hazards and are known to the staff.
- g. Incidents, accidents and near misses are reported and analysed to identify causes and the analysis is used to improve systems and processes, e.g. needle stick injuries.
- h. Staff is provided with and use protective equipment, e.g. gloves, aprons, masks.
- i. Staff is trained in fire safety and other emergencies and drills are practised regularly.
- j. Staff health is protected by the provision of immunization for infections such as Hepatitis A and B and influenza.

4.13 Client/Patient feedback

Client/Patient feedback is collected and used to improve services.

- a. Clients/Patients have access to a culturally appropriate feedback mechanism, e.g. suggestion box, questionnaires, regular interviews with clients by an independent person.
- b. Data collected on client/patient satisfaction with services and treatment is analyzed and used to improve services.

4.14 Complaint Handling

Clients/Patients have the right to complain about services and treatment and their complaints are investigated in a fair and timely manner.

- a. Clients/Patients are informed of their right to express their concerns or complain either verbally or in writing.
- b. A documented process which is fair and timely is used for collecting, reporting and investigating complaints.
- c. Clients/Patients are informed of the progress of the investigation at regular intervals and are informed of the outcome.

4.15 Continual Improvement

The Service identifies opportunities to continuously improve its processes and services, makes improvements and evaluates their effectiveness.

- d. Performance indicators for priority diseases and key processes are measured, reported and used for continuous improvement.
- e. Performance data from activities such as audits, complaints, incident reports, satisfaction surveys and risk assessments are collected, analysed and used to identify improvement opportunities. This is coordinated by the quality group.
- f. Improvements are planned, appropriate action is taken, the effectiveness of the action is evaluated and the results are fed back to staff and clients/patients.
- g. All relevant legal requirements are identified and compliance is monitored.

5. REQUIREMENTS FOR SERVICE PROVISION

5.1 Accessibility to Health Services

The facility and the services provided are easily accessible to the catchment area population

- a. The facility is located within 5 km of the patient.
- b. Costs involved in using the services are addressed in the annual plan and steps are taken to minimize costs, such as fees, drugs, lost income, and transportation costs.

- c. Major obstacles affecting access for clients/patients to the facility and its services are addressed in the annual plan and steps are taken to minimize them, e.g.
 - i. The attitude of employees working at the facility;
 - ii. The perception of the need and utility of health care by the community;
 - iii. Cultural constraints on clients about using the facility and its services.

5.2 Accessibility to the Information

A list of available services and applicable fees is posted where the clients/patients can see them.

- a. A poster with listed services, opening times and emergency contacts during closing times is displayed in a prominent place where the clients/patients can see it. The text is in an understandable format, e.g. local or national language.
- b. A list with all fees and possible exemptions is displayed in a prominent area where the clients/patients can see it. The text is in an understandable format, e.g. local or national language.

5.3 Behaviour with client/patient and their attendant

Clients/Patients and their attendants are received in a friendly and respectful manner irrespective of their sex, age, race, religion or physical appearance

- a. Clients/Patients are treated in a kind, patient and respectful manner at all stages from registration through to end of service.
- b. The healthcare provider uses open ended questions (why, who, what, when, how) to obtain information from clients/patients.
- c. The healthcare provider listens carefully to what the clients/patients say and does not jump to conclusions.
- d. The healthcare provider explains to the client/patient the diagnosis, care management, and follow-up.
- e. The healthcare provider takes feedback from the client/patient to ensure the client/patient understands the message communicated.

5.4 Priority on service provision

Providers give priority to extremely sick clients/patients and those of extreme age (early new-born's and elderly).

- a. A system using the time of arrival recorded on the registration chit is used to prioritize clients/patients.
- b. The order prioritizes extremely sick clients/patients first, those of extreme ages (elderly and babies) second and then others.
- c. Extremely sick clients/patients are seen by the healthcare provider within five minutes, and those of extreme ages within 15 minutes.

5.5 Emergency cases

Providers use a defined process for referring emergency cases.

- a. SOPs exist for identification of types of clients/patients who need to be referred.
- b. A referral form provides sufficient information to allow continuity of care.
- c. When possible transportation to the referral facility is provided.
- d. In other cases, the Service provides some type of assistance for moving a sick client/patient to a referral facility such as communication to the next level, or arranging community transport.
- e. A copy of the referral form is kept at the facility.

5.6 Dealing with non-priority patient

Non-priority clients/patients wait no more than one hour after arrival at the facility before being seen by the provider.

- a. A system is used to prioritize the order in which non-priority clients/patients are seen on a first-come first-serve basis.
- b. Waiting times are no more than one hour and are monitored.
- c. Waiting times are analyzed and results used to improve services.

5.7 Privacy

The privacy of patients/clients is ensured during consultation and examination.

- a. Consultations and examinations are held behind curtains/screens at all times.
- b. Healthcare providers ensure privacy at the time of consultation.

5.8 All clients/patients receive appropriate assessment, diagnosis, plan of care, treatment and care management, and follow-up

- a. The registration chit is completed promptly for all clients/patients.
- b. The time the client/patient arrives is documented on the registration chit and monitored
- c. Basic assessment is undertaken and includes temperature, blood pressure, and symptom identification.
- d. Basic assessment for children under five includes weight, immunization status, temperature, level of consciousness and symptom identification.
- e. A client/patient history is taken and documented.
- f. Treatment and care management is provided in accordance with the assessment, test results, diagnosis and care management guidelines.
- g. Referrals to other services are made when required.
- h. Appointments for future care are made.
- i. Results of previous care are used in follow-up visits.

5.9 National and Provincial Treatment guidelines are available and used for those services listed as offered.

- a. Healthcare providers provide technically correct services according to guidelines for but not limited to the following areas:
 - i. First Aid and Emergency care, Injury management, minor surgical procedures
 - ii. IMCI, ANC, Delivery, PNC, Family planning
 - iii. Malaria, TB & DOTS, HIV/ AIDS VCT, STD, Diarrhoea, Polio, Hepatitis, HIV/AIDS, Measles, ARI, Hypertension, Diabetes, Anaemia, Common skin problems, EPI
 - iv. Dental care.
- b. Staff is trained to follow these guidelines.
- c. Justification is available for variations from the guidelines.

5.10 All children who visit the facility have their weight plotted correctly on their health card and have their immunization status checked.

- a. All under five children coming to the facility are weighed.
- b. Weight is accurately plotted on the child's health card and follow-up action taken based on the plot.
- c. Immunization status is checked and missing immunizations given
- d. Weight and vaccination information are given to the parent/carer.

5.11 Healthcare providers regularly educate their clients on health issues in a way that is easy to understand.

- a. Healthcare providers conduct group health education sessions at least four times a month.
- b. Healthcare providers use the following materials during client/patient counselling/education sessions: posters, family planning material, brochures, leaflets, flipcharts and cue cards.
- c. Health education messages (posters and charts with pictures and minimal text) are visibly posted in prominent areas within the facility.
- d. Health education written material is available for clients/patients to read and take home.

5.12 Clients/Patients are given accurate information about their medication regime to enable them to manage it.

- a. The healthcare provider/dispenser instructs clients/patients about the medication, the amount of medication to take, what time to the day it should be taken and for how long it should be taken.
- b. The healthcare provider/dispenser checks that the client/patient understands the instructions.

5.13 Staff follows correct aseptic techniques and washes their hands between clients/patients.

- a. Health workers perform the following aseptic procedures in line with SOPs or guidelines: wound dressing, suturing, catheterization, injections, intravenous infusion and dental extraction.
- b. Soap (where possible liquid soap) and water or antiseptic gel are available at the washing point(s) in or near the consulting/examination room(s) and a clean hand

towel or alternate is available.

- c. Hand washing instructions are posted above the washing point(s).
- d. Healthcare providers wash their hands between clients/patients and between procedures.

5.14 Rational prescribing is practised to minimize the risk of drug resistance, ensure appropriate treatment and enable cost-effective care.

- a. An essential drug list is available and followed.
- b. Good prescribing practice guidelines for antibiotics are available and followed.
- c. The probable diagnosis is written on the prescription.
- d. If the diagnosis changes as a result of follow-up assessment or test results the prescription is reviewed.

5.15 Essential drugs and supplies are available at all times during open hours.

- a. Stock cards are up to date and correspond to physical stock.
- b. There is a stock of the essential drugs.
- c. There is a process for checking date of expiry.
- d. No expired drugs are in stock.

5.16 Cold chain vaccine

The cold-chain for vaccines is maintained

- a. A Cold Chain procedure for vaccines is used and includes clear directions on the following practices.
 - i. Vaccine stock management including vaccine storage, potency, stock quantities, stock records, and arrival report
 - ii. Equipment for vaccine transport and storage
 - iii. Maintenance of equipment
 - iv. Control and monitoring of temperature
 - v. Cold chain during immunization sessions
 - vi. Syringes, needles and sterilization and
 - vii. Breakdown of equipment and emergency actions to minimize risks.

5.17 Single use item

Items for single use are not reused.

- a. Disposal systems and processes for single-use items are available and used.

5.18 Sharps and needles are used and disposed of safely.

- a. Labelled needle safety boxes are available in the examination, injection and dressing rooms.
- b. Staff safely disposes of sharp objects and needles in the containers provided.

SCHEDULE-III

IHRA Standards for Clinical Laboratories

1. SCOPE

This IHRA Standards prescribe the management and service provision standards for clinical laboratories. For laboratories existing within hospitals and healthcare facilities will be covered through the laboratory component of that healthcare establishment's standards.

2. NORMATIVE REFERENCES

IHRA 1003:2020 IHRA Standards for Clinical Laboratories

3. TERMS AND DEFINITIONS, AND ABBREVIATIONS

For terms and definitions, please see IHRA 1010:2020 (IHRA Standards – Terms and Definitions on Healthcare).

4. STANDARDS AND INDICATORS

Each standard is described through indicator(s), which are color coded as red (highly critical) and yellow (critical).

4.1 Responsibilities of Management

Standard 1: The laboratory is easily identifiable.

Indicator 1: The laboratory is identifiable with name on a sign board.

Indicator 2: The laboratory sign board conforms to the prescribed local legal standards.

Indicator 3: The laboratory is registered with Islamabad Healthcare Regulatory Authority.

Indicator 4: The laboratory is licensed with Islamabad Healthcare Regulatory Authority.

Indicator 5: Associated collection centers are reflected in the Registration Certificate/ License issued by the Islamabad Healthcare Regulatory Authority.

Indicator 6: Signed valid MOU, showing linkage with any other Laboratory or organization for referral of specialized tests, exists.

Standard 2: A technically qualified and experienced individual heads the laboratory.

Indicator 7: The individual heading the laboratory is a qualified pathologist having valid professional registration and requisite experience.

Standard 3: Responsibilities of Management are defined.

Indicator 8: Those responsible for lab management lay down the laboratory's mission statement.

Indicator 9: Those responsible for management lay down a detailed laboratory policy and standard operating procedures (SOPs).

Indicator 10: Those responsible for management develop an emergency policy and standard operating procedures.

Indicator 11: Those responsible for management approve sufficient budget and allocate the resources required to accomplish the mission.

Indicator 12: Those responsible for management establish the laboratory's organogram.

Indicator 13: Those responsible for management, appoint the section heads in the laboratory.

Indicator 14: Those responsible for management, support research activities.

4.2 Facility Management and Safety

Standard 4: The management is aware of and complies with the laws, bylaws, rules and regulation, and facility inspection requirements under the relevant building and associated codes applicable to laboratory.

Indicator 15: The management is conversant with the relevant laws and regulations and knows their applicability to the laboratory.

Indicator 16: The management regularly updates any amendments in the prevailing relevant laws and rules.

Indicator 17: The management ensures implementation of these requirements.

Standard 5: Facility work flow design conforms to scope of services.

Indicator 18: Space allocation and effective separation exists between administration and technical laboratory areas.

Indicator 19: Measures are taken to restrict movement of the technical staff working in different sections of the laboratory.

Standard 6: The laboratory has plans for fire and non-fire emergencies within the sections.

Indicator 20: Plans and provisions for early detection of fire and non-fire emergencies exist.

Indicator 21: Provisions for abatement of fire and non-fire emergencies exist.

Indicator 22: Provisions for containment of fire emergencies exist.

Indicator 23: Displayed safe exit points in case of fire and non-fire emergencies exist. **Indicator 24:** Mock drills are held at least twice in a year.

Indicator 25: Staff members are trained for their role in case of such emergencies.

4.3 Human Resource Management

Standard 7: Staff deployment is in accordance with the scope of laboratory work.

Indicator 26: Job description for every post is identified and documented.

Indicator 27: Eligibility criteria, regarding qualification and experience for every job is available.

Indicator 28: Recruitments are according to laid down eligibility criteria.

Standard 8: The staff members joining the laboratory are oriented to the laboratory environment, the laboratory sections and their individual jobs.

Indicator 29: An appropriate orientation plan exists for newly inducted employees.

Indicator 30: Each staff member is made aware of laboratory wide policies and procedure as well as section/unit/services/program specific policies and procedures.

Indicator 31: Each staff member is made aware of their rights and responsibilities.

Indicator 32: All employees are oriented on dealing with patients and responsibilities.

Standard 9: An annual appraisal system for evaluating the performance of employees exists as an integral part of the human resource management process.

Indicator 33: Well documented performance appraisal tools exist in the laboratory.

Indicator 34: All the employees/consultant/ students/ voluntary workers are made aware the performance appraisal tools at the time of induction.

Indicator 35: The appraisal is used as a tool for further development

Indicator 36: Performance appraisal is carried out at pre- defined intervals and is documented.

Standard 10: Documented personal record for each staff member exists.

Indicator 37: Personal files are maintained in respect of all full time/part time employees, which include records of the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel.

Standard11: In- service staff capacity building record is documented.

Indicator 38: In-service training plan for staff members is available.

Indicator 39: All records of in-service training and education are contained in the personal files.

Standard 12: There is a process for collecting, verifying and evaluating the credentials (education, registration, training and experience) of laboratory professionals, including doctors, technologists and others.

Indicator 40: A system for the verification of documents of and certificates of employees exists in the laboratory

Indicator 41: Verification of credentials/documents is done in the laboratory for any newly added qualification/training certificate.

4.4 Management of Equipment and Reagents

Standard 13: Ensure quality of equipment and reagents through standardized procurement procedures.

Indicator 42: The procurement procedure of the laboratory is laid down.

Indicator 43: Specification for all the equipment and reagents/kits/consumables to be purchased is documented.

Indicator 44: Procurement orders are clear, dated and signed. **Indicator**

45: Procured items are regularly entered into stock registers.

Standard 14: Safe handling and storage of laboratory reagents.

Indicator 46: Documented policies and procedures guide the safe storage and use of reagents to ensure the continuing quality, integrity and confidentiality of sample materials, documents, equipment, reagents, consumables, records, results, and any other items that could affect quality of examination results.

Indicator 47: An accurate and up-to-date inventory of reagents, biological agents and toxins is maintained.

Indicator 48: The policies of reagent management include a procedure of alert for near expiry reagents.

Indicator 49: Labeling of reagents is as per SOPs.

Standard 15: Comprehensive procedure for equipment management and maintenance exist in the laboratory.

Indicator 50: Logbooks of all equipment are available.

Indicator 51: Regular periodic maintenance and calibration record of all the equipment is available in the logbooks.

Indicator 52: Document and relevant log sheet is displayed on each equipment.

Indicator 53: Emergency contact number/s is/are displayed on all equipment.

Indicator 54: Equipment inventory is maintained having following information:

- a) Identity of the equipment
- b) Manufacturer's name, type identification, and serial number or other unique identification
- c) Contact information for the supplier or the manufacturer and on-call service
- d) Date of receiving and date of entering into service
- e) Location
- f) Condition when received (E.g., new, used or reconditioned)
- g) Manufacturer's instructions

h) Records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory

i) Up to date, current instructions on use, safety and maintenance of equipment, including relevant manuals and directions for use provided by the manufacturer

Indicator 55: Equipment are registered with Drugs Regulatory Authority of Pakistan (DRAP).

4.5 Recording and Reporting System

Standard 16: The Laboratory has a complete accurate laboratory record for every patient.

Indicator 56: Electronic record of every patient is maintained.

Indicator 57: Every laboratory record has a unique identifier.

Indicator 58: The record provides an up-to-date and chronological account of each patient's record of tests.

Indicator 59: Only authorized person to make entries in the laboratory record and results shall be reviewed by authorized person before they are released.

Indicator 60: Every laboratory record entry is dated, timed and the person making entries can be identified.

Standard 17: A comprehensive reporting system exists in the laboratory.

Indicator 61: A computerized reporting system is available.

Indicator 62: Critical results and notifiable diseases are reported.

Standard 18: The laboratory record supports continuity of patient care.

Indicator 63: Minimum reporting time for every test is documented.

Indicator 64: Reports are accessible to individual patients through a specific code.

4.6 Quality Assurance

Standard 19: The laboratory has a comprehensive and documented quality assurance (QA) program.

Indicator 65: Laboratory has quality assurance (QA) SOPs.

Indicator 66: There is a designated focal person responsible for quality assurance (QA)

activities in the laboratory.

Indicator 67: Quality assurance (QA) SOPs are communicated and coordinated among the staff.

Standard 20: External quality assurance (EQA) compliance procedure and tools are available in the laboratory.

Indicator 68: External quality assurance (EQA) of the laboratory is ensured through external assessment by national/internally recognized bodies.

Indicator 69: Records of external quality assurance (EQA) reports are maintained.

Standard 21: Internal quality assurance (IQA) is ensured through standardized laboratory practices.

Indicator 70: Policies and procedures guide the safe collection of specimens.

Indicator 71: Policies and procedures guide the identification and proper labeling of specimens.

Indicator 72: Policies and procedures guide the safe handling of specimens.

Indicator 73: Policies and procedures guide the safe transportation of specimens.

Indicator 74: Policies and procedures guide the safe processing of specimens.

Indicator 75: Policies and procedures guide the safe disposal of specimens.

Indicator 76: Availability of controls for internal quality assurance (IQA) is ensured.

Indicator 77: Process cycle records are maintained.

Standard 22: Continuous laboratory improvement is documented.

Indicator 78: Gaps are identified through QA reports and used as tools for improvement.

Indicator 79: Corrective actions are implemented upon identification of gaps.

Indicator 80: Measures are taken to minimize recurrence of errors.

4.7 Biosafety and Biosecurity

Standard 23: The laboratory has a comprehensive and coordinated biosafety program.

Indicator 81: Availability of laboratory biosafety SOPs.

Indicator 82: Biosafety SOPs are communicated to the laboratory staff.

Indicator 83: The laboratory has a designated qualified technical for ensuring biosafety activities.

Indicator 84: Regular biosafety monitoring reports are generated in the laboratory.

Standard 24: Continuous staff biosafety measures are ensured and documented.

Indicator 85: The laboratory has appropriate consumable, equipment and facilities to ensure bio-safety.

Indicator 86: All staff involved in the handling and disposal of laboratory waste shall receive regular vaccination.

Indicator 87: Annual medical check-up of all staff is documented.

Standard 25: Patient and visitor biosafety is ensured and documented.

Indicator 88: Proper ventilated waiting areas for patients and visitors are available.

Indicator 89: Patients and visitors are not allowed inside the laboratory working area.

Standard 26: There is a documented procedure of bio-risk management.

Indicator 90: All incident reports are documented.

Indicator 91: Required disinfectants/spill kits are available in the laboratory.

Standard 27: Measures to ensure biosecurity in the laboratory are practiced.

Indicator 92: Only authorized persons are permitted to enter the sample storage area.

Indicator 93: Any transportation of samples is properly recorded.

Standard 28: The laboratory has a well-designed, comprehensive and coordinated waste management plan.

Indicator 94: Written laboratory waste management SOPs are available.

Indicator 95: Waste management SOPs are communicated to the laboratory employees.

Indicator 96: The laboratory has appropriate consumable, collection and handling systems and equipment for waste management.

Indicator 97: Contracts with waste disposal service organizations are available.

Indicator 98: Waste transported from collection centers for final disposal is recorded.

4.8 Access, Assessment and Continuity of Care

Standard 29: Laboratory services are easily accessible.

Indicator 99: The laboratory's location for collection of samples is easily accessible.

Indicator 100: Basic facilities are accessible in the laboratory.

Indicator 101: There are clean toilets/washrooms with bolts, preferably separate for males and females.

Indicator 102: Facilitated toilets for disabled patients with wheel chair access are available in the laboratory.

Indicator 103: Disabled patients are facilitated for phlebotomy.

Indicator 104: Directional arrows pointing towards various important areas for patients are displayed in the laboratory.

Standard 30: Laboratory services are provided as portrayed/claimed.

Indicator 105: Laboratory services being provided are displayed.

Standard 31: A comprehensive audit system for laboratory performance assessment exists in the laboratory.

Indicator 106: There is a system to monitor and measure the performance of the laboratory biannually against the stated mission.

Indicator 107: Procured kits and their consumption are compared with test performed during laboratory performance audit.

4.9 Care of Patients

Standard 32: Emergency handling of patients is guided by protocols.

Indicator 108: Protocols for providing first aid/emergency care to the patients are documented.

Indicator 109: Relevant contact numbers for emergency evacuation/referral are available in the laboratory.

Standard 33: Sentinel events are intensively analysed.

Indicator 110: The laboratory has defined sentinel events.

Indicator 111: Sentinel events are intensively analyzed when they occur.

Standard 34: The laboratory policies and procedures support domiciliary services to the patients (where applicable/claimed).

Indicator 112: The laboratory is equipped with means of communication and transport services for home-based patient sample collection.

Indicator 113: The laboratory has appropriate means of collection and transportation of home-based samples.

4.10 Patient Rights and Education

Standard 35: A system exists for obtaining consent when it is required.

Indicator 114: The laboratory has listed those situations where specific informed consent is required.

Indicator 115: The policy describes who can give consent when a patient is incapable of independent decision-making.

Standard 36: Patient and families have a right to information on expected costs.

Indicator 116: The tariff list is available to patients.

Indicator 117: Patient/families are informed about the additional reports which are generated or included in the report with the same sample and cost.

Standard 37: Patient rights for appeal, complaints and confidentiality are protected.

Indicator 118: Patient's complaints are accepted by the laboratory and properly registered.

Indicator 119: Proper actions and remedial measures are taken in response to patients' complaints.

Indicator 120: Confidentiality of patient record is maintained.

SCHEDULE-IV

STANDARDS AND INDICATORS

1. Responsibilities of Management

Standard 1: The clinic is identified as an entity and easily accessible.

Indicator 1: The clinic is identifiable with the name and Registration/ license number on the sign boards.

Indicator 2: The patient/client has easy access to the clinic. **Indicator 3:** The dental clinic is registered/licensed with the IHRA.

Indicator 4: Door plate clearly displays name and qualifications of the dental surgeon. **Indicator 5:** The staff on duty uses identity badges.

Indicator 6: Consultation hours are displayed.

Standard 2: The manager and the healthcare service providers at the clinic is/are suitably qualified.

Indicator 7: The clinic manager is duly designated and has requisite qualifications.

Indicator 8: PMC & IHRA Registration certificate of the dental surgeon is displayed

Standard 3: Clinic premises support the scope of work/services.

Indicator 9: The size/premises of the dental clinic is as per the minimum requirement.

Indicator 10: The dental clinic has adequate facilities for the comfort of the patients.

Indicator 11: The dental clinic has adequate arrangements to maintain the privacy of patients during consultation/examination/procedures.

Standard 4: The responsibilities of the management are defined.

Indicator 12: The dental clinic management intimates any change in scope or portrayal of services, the location of the HCE or the service providers etc to the IHRA.

Indicator 13: The dental clinic management addresses social and community responsibilities.

2. Facility Management and Safety

Standard 5: The dental staff is aware and complies with the relevant laws, rules, regulations, bylaws inspection requirements under the applicable codes.

Indicator 14: The clinic plans for equipment in accordance with its scope of services. **Indicator 15:** The clinic management is conversant with the relevant laws and regulations.

Indicator 16: The management ensures implementation of relevant laws.

Indicator 17: There is mechanism to regularly update licenses, registrations and certifications.

Indicator 18: The staff has the knowledge about early detection and containment of fire and non-fire emergencies.

Indicator 19: Arrangement to combat fire and non-fire emergencies are in place.

Standard 6: The clinic has a program for management of dental and support service.

Indicator 20: The clinic plans for equipment in accordance with its scope of services. **Indicator 21:** Dental equipment is selected by a collaborative process.

Indicator 22: Qualified and trained personal operate and maintain the equipment.

Indicator 23: Equipment is periodically inspected, serviced and calibrated to ensure its proper functioning.

3. Human Resource Management

Standard 7: There is documented personnel record of dental surgeons and staff.

Indicator 24: Personal record/credentials in respect of all staff are maintained.

Standard 8: The employees joining the dental clinic/practice are oriented to the environment, respective sections and their individual jobs.

Indicator 25: Each regular/part time employee, student and voluntary worker is appropriately oriented to the overall environment of the dental clinic/relevant section/units/service and program policies and procedures.

Indicator 26: Each regular/part time employee is made aware of the job description.

Indicator 27: Performance evaluations are based on the JDs.

Indicator 28: Each regular/part time employee is made aware of his/her rights and responsibilities and patient rights and responsibilities.

4. Information Management Systems

Standard 9: Patient clinical record is maintained at the dental clinic.

Indicator 29: Every patient's record has a unique identifier and particulars for identification.

Indicator 30: Only authorized persons make entries in the record.

Indicator 31: Every record entry is dated, time and signed.

Indicator 32: The record provides an up-to-date and chronological account of patient care.

5. Quality Assurance/Improvement

Standard 10: The dental clinic has a quality assurance/quality improvement system in place.

Indicator 33: Service provision is as per portrayal.

Indicator 34: A quality improvement system is in practice.

Standard 11: The clinic identifies key indicators to monitor the inputs, process and outcomes which are used as tools for continual improvement.

Indicator 35: Monitor includes appropriate patient assessment.

Indicator 36: Monitoring includes safety and quality control programs of the diagnostic services.

Indicator 37: Monitoring includes all invasive procedures.

Indicator 38: Monitoring includes adverse drug events.

Indicator 39: Monitoring includes use of anesthetics.

Indicator 40: Monitoring includes availability and consent of the clinic records.

Standard 12: Sentinel events are assessed and managed.

Indicator 41: The clinic has enlisted the sentinel events to be assessed and managed.

6. Assessment and Continuity of Care

Standard 13: Portrayed services conform to the legal provision.

Indicator 42: The services being provided at the clinic are displayed as per code of Ethics.

Indicator 43: specialized services being provided conform to the standards.

Indicator 44: The use and maintenance of specialized equipment conforms to the standards.

Indicator 45: Dental laboratory services, provided, conform to the respective standards.

Indicator 46: Dental radiological diagnostic services, if being provided, conform to the respective standards.

Indicator 47: Dental health education is provided as per guidelines.

Indicator 48: Preventive services are provided as per guidelines.

7. Care of Patients

Standard 14: The clinic has a well-established patient management system.

Indicator 49: The clinic has an established registration and guidance process. **Indicator 50:** Standard/Ethical practice is evident from the patient record. **Indicator 51:** The clinic has referral SOPs.

Indicator 52: The clinic has list of contact numbers of the referral facilities, medico legal authorities, concerned police station, ambulance/rescue services and social services organizations.

Standard 15: The clinic has essential arrangements for providing care to emergency cases.

Indicator 53: The clinic has essential arrangements to cater for emergency care.

8. Management of Medication / Dispensing

Standard 16: Prescribing practices conform to the standards.

Indicator 54: Standards for prescription writing are followed.

Indicator 55: Prescriptions are clear, legible, dated, timed, named / stamped and signed.

Indicator 56: Prescriptions are provided to the patients.

Standard 17: Storage and dispensing/usage confirms to the guidelines.

Indicator 57: Medicines/disposable/dental materials are stored as per guidelines.

Indicator 58: Expiry dates/ shelf life are checked prior to administering, as applicable. **Indicator 59:** Labeling requirements are implemented.

Indicator 60: Dispensing/utilization is by an authorized person.

9. Patient Rights/Responsibilities and Education

Standard 18: There is a system for awareness/education of patients and others regarding the charter of Rights and Responsibilities for compliance.

Indicator 61: The charter of Rights and Responsibilities are displayed and patient/families are guided on it.

Standard 19: PRE-2: There is a system for obtaining consent for treatment.

Indicator 62: The dental surgeon obtains consent from patient before examination.

Indicator 63: The clinic has listed those situations where specific informed consents required from a patient or family.

Standard 20: Patient and family have a right to information about expected costs.

Indicator 64: The patient/family is informed about the cost of treatment.

Standard 21: Patients and families have a right to refuse treatment and lodge a complaint.

Indicator 65: Patients and families have a right to refuse the treatment.

Indicator 66: Patients and families have a right to complain and there is a mechanism to address the grievances.

10. Infection Control

Standard 22: The clinic has a well-designed, comprehensive and coordinated infection control system aimed at reduced/eliminating risks to patients, visitors and care providers.

Indicator 67: The infection control plan is documented which aims at preventing

and reducing the risk of nosocomial infections.

Indicator 68: The clinic has designated staff and defined responsibilities for infection control and waste management activities.

Indicator 69: The clinic has appropriate consumable, collection and handling systems, equipment and facilities for control of infection.

Indicator 70: All staff involved in the creation, handling and disposal of dental/clinical waste shall receive regular training and ongoing education in the infection control and safe handling of dental waste.

Standard 23: There are documented procedures for sterilization activities in the clinic.

Indicator 71: There is adequate space available for sterilization activities.

Indicator 72: Regular validation tests for sterilization are carried out and documented. **Indicator 73:** There is an established procedure for recall in case of breakdown in the sterilization system.

SCHEDULE-V

Standards & Indicators

1.1 Responsibilities of Management (ROM)

Standard-1: The HCE is identifiable as a legal entity and easily accessible to the patients and the surveyors

Indicator-01: The HCE is identifiable with a signboard conforming to the legal requirements and depicting Name and IHRA Registration / License Number on the Sign Board/s.

Indicator-02: The HCE is registered/licensed with IHRA.

Indicator-03: The HCE is easily reachable.

Standard-2: The Staff on duty is identifiable

Indicator-04: The Staff on duty uses the authorized Identity Badge.

Indicator-05: Door plate/s at clinics/offices clearly displays name, qualification/s, and designation/s of the staff on duty.

Standard-3: The HCE premises support the scope of work / services

Indicator-06: The HCE premises have demarcated areas according to the scope of work/services.

Indicator-07: HCE has adequate facilities/civic amenities for the comfort of the patients and attendants and these are adequately maintained.

Indicator-08: The HCE has adequate arrangements for the privacy of patients during consultation, examination, procedures etc.

Indicator-09: The HCE has arrangements to provide safe recreational activities.

Indicator-10: The HCE provides psychosocial rehabilitation services.

Standard-4: Responsibilities of management are defined.

Indicator-11: The management of the facility has laid down mission statement of the HCE.

Indicator-12: Those responsible for management establish the HCE organogram.

Indicator-13: The management ensures appointment of competent professionals according to organogram.

Indicator-14: Those responsible for management appoint a technically qualified and experienced professional to head the HCE.

Indicator-15: Those responsible for management lay down the overall Policy, Standing Orders and SOPs.

Indicator-16: The management is responsible for arranging/designating a substitute when particularly the head or any section in charge is absent due to any reason.

Indicator-17: Those responsible for management lay down standing orders and SOPs for emergency situations.

Indicator-18: Those responsible for management lay down security standing orders and SOPs.

Indicator-19: Those responsible for management monitor and measure the performance of the HCE against the assigned roles.

Indicator-20: The HCE management addresses the HCE's social and community responsibilities.

Indicator-21: Those responsible for management support research activities.

Standard-5: The management ensures functioning of the HCE according to relevant statutes.

Indicator-22: The management ensures availability of the applicable laws/by-laws/codes/rules/ regulations.

Indicator-23: The management is conversant with the relevant laws/bylaws/codes/rules/regulations and knows their applicability to the HCE.

Indicator-24: The management regularly updates any amendments in the prevailing relevant laws/Rules/ regulations/SOPs and SMPs.

Indicator-25: The management ensures implementation of the applicable laws/rules/regulations/SOPs and SMPs.

1.2. Facility Management and Safety (FMS)

Standard-6: Facility design supports the scope of work.

Indicator-26: There is effective separation between different areas including administrative, clinical consultation, Indoor and counseling etc.

Indicator-27: HCE design supports the arrangements for the security of premises against unauthorized entry/exit.

Standard-7: The HCE maintains a safe and secure environment for patients/attendants and the staff.

Indicator-28: The HCE has arrangements to ensure physical safety of patients/attendants in the HCE.

Indicator-29: There are arrangements to ensure safety / security of food / eatables for resident patients/attendants/staff in the HCE.

Indicator-30: There are arrangements to ensure safety of medicines/drugs for resident patients in the HCE.

Indicator-31: There are arrangements for provision of clean clothing/linen to the resident patients.

Standard-8: The HCE has plans for fire and non-fire emergencies.

Indicator-32: There is plan and provisions for early detection of fire and non-fire emergencies.

Indicator-33: There are provisions for abatement of fire and non-fire emergencies.

Indicator-34: Provisions are made for containment of fire and non-fire emergencies.

Indicator-35: Safe exit points in case of fire and non-fire emergencies are displayed.

Indicator-36: Mock drills are conducted at least once in a year.

Indicator-37: Staff members are trained for their role in case of such emergencies.

Standard-9: The HCE has a system for management of equipment for clinical and support services.

Indicator-38: The HCE has equipment in accordance with the scope of its services.

Indicator-39: Equipment is operated and maintained by qualified/trained personnel.

1.3. Human Resource Management (HRM).

Standard-10: Staff deployment is in accordance with scope of services.

Indicator-40: Eligibility criteria regarding qualification and experience for each job are available.

Indicator-41: Recruitment is made according to the laid down criteria.

Indicator-42: Job description for every post is defined and documented.

Indicator-43: Requisite staff is available at HCE for provision/supervision of prescribed psychiatric and/or addiction treatment services.

Standard-11: Staff members joining the HCE are oriented to HCE environment, different sections and their Individual jobs.

Indicator-44: There is an appropriate orientation plan for newly Inducted staff.

Indicator-45: Each staff member is aware of his/her rights and responsibilities.

Indicator-46: All employees are educated with regard to patient's rights and responsibilities.

Indicator-47: Staff receives refresher training/certification to continue to perform the jobs effectively.

Standard-12: An appraisal system for evaluating the performance of employees exists as an integral part of the Human Resource Management.

Indicator-48: There is a well-documented performance appraisal system and tools in the HCE.

Indicator-49: All of the employees / Consultants / Students / voluntary workers are made aware of the performance appraisal tools at the time of Induction.

Indicator-50: The appraisal is used as a tool for further development.

Indicator-51: Performance appraisal is carried out at pre-defined intervals and is documented.

Standard-13: Documented personal record for each staff member exists.

Indicator-52: Personal files are maintained in respect of all full time/part time employees.

Standard-14: There is a system for collecting, verifying and evaluating the credentials.

Education, registration, training & experience of professionals including doctors, and others

Indicator-53: System for verification of documents and certificates of employees exists in the HCE.

Indicator-54: Only medical professionals permitted by law/regulation provide patient care without supervision.

1.4. Information Management System (IMS).

Standard-15: The HCE has a complete and accurate medical record for every patient.

Indicator-55: Every medical record has a unique identifier.

Indicator-56: The staff authorized to make entries in the medical record is reflected in the HCE's policy/SOPs and is identifiable.

Indicator-57: Every medical record entry is dated, timed and signed.

Indicator-58: Complete medical record of the patients is maintained at HCE.

Indicator-59: The progress notes are recorded by the professionals responsible for the care of the patient.

Indicator-60: Every dormant record has a discharge summary.

Indicator-61: The SOPs for safety and security of patient record exist and are practiced.

Indicator-62: Authorized care providers have access to current and past medical records.

Standard-16: The HCE regularly carries out review of medical records.

Indicator-63: The medical records are reviewed regularly / periodically.

Indicator-64: The review focuses the timeliness, legibility and completeness of both active/current and discharged patient (closed/dormant) records.

Indicator-65: Any deficiency, found in the review and corrective measure taken, is documented.

1.5. Continuous Quality Improvement (CQI).

Standard-17: The HCE has a structured Quality Improvement system in place.

Indicator-66: A comprehensive plan covering ALL the major elements related to quality improvement is developed, implemented and maintained by a notified CQI Committee.

Indicator-67: There is a designated Individual for coordinating and implementing the quality improvement program.

Indicator-68: The CQI program is communicated and coordinated amongst all the employees of the HCE, through proper training mechanism.

Indicator-69: The quality improvement program is a continuous process and updated at least once in a year.

Standard-18: The monitoring system for CQI exists at the HCE.

Indicator-70: Monitoring includes appropriate patient assessment.

Indicator-71: Monitoring includes adverse drug events.

Indicator-72: Monitoring includes availability and content of medical records.

Indicator-73: Monitoring includes recommendations from appropriate services concerning follow-up or aftercare.

Standard-19: Sentinel events are assessed and managed.

Indicator-74: The HCE has defined sentinel events.

Indicator-75: Sentinel events are intensively analyzed when they occur.

1.6. Access, Assessment and Continuity of Care (AAC)

Standard-20: Services are provided as portrayed / claimed.

Indicator-76: Only the services registered with IHRA are provided and the same are displayed at the HCE.

Indicator-77: Health education is provided as per guidelines.

Indicator-78: The preventive services are provided as per guidelines.

Standard-21: HCE has a well-established patient management system.

Indicator-79: The HCE employs a comprehensive patient management process.

Indicator-80: An initial assessment is made in order to diagnose and prioritize interventions in a coordinated treatment plan.

Indicator-81: The assessment of patients employs standard tools for classification of mental disorder.

Indicator-82: Patients being evaluated for addiction also undergo an assessment of mental health status and possible psychiatric disorders.

Indicator-83: Assessment of female patients includes their gynecological status.

Standard-22: Adequate diagnostic facilities are in place/accessible.

Indicator-84: Laboratory/testing arrangements to facilitate the assessment of patients are available.

Indicator-85: Imaging services are available / accessible as per the clinical requirements of the patients.

Indicator-86: Only those diagnostic services are provided / accessed which comply the prescribed minimum standards.

1.7. Care of Patients (COP).

Standard-23: Emergency services are guided by policies, procedures and applicable laws and regulations.

Indicator-87: Documented SOPs for emergency care exist.

Indicator-88: Policies address handling of medico-legal cases.

Indicator-89: SOPs guide the prioritization of patients for initiation of appropriate care.

Indicator-90: Staff members are familiar with the SOPs for care of emergency patients and trained on the same and the patients receive care in consonance with the SOPs.

Standard-24: Policies and procedures guide the admission/detention and discharge of the patients.

Indicator-91: The reasons for admission/detention must be clearly documented as stated by the patient and/or others significantly involved.

Indicator-92: Admission/detention, discharge or referral to another HCE is documented.

Standard-25: Patient management is planned on the basis of assessment & diagnosis.

Indicator-93: A substantiated diagnosis is established and documented.

Indicator-94: A complete neurological assessment is also undertaken when indicated.

Indicator-95: A comprehensive treatment is planned for each female patient on the basis of her assessment including gynecological status.

Indicator-96: The treatment plan is reviewed, on the basis of patient's strengths and disabilities.

Indicator-97: The treatment provided is comprehensibly entered in the medical records.

Indicator-98: Contact with visitors is monitored/supervised and possibly restricted, particularly in the early stages of treatment.

Indicator-99: Psychotherapy services are provided as prescribed.

Indicator-100: SOPs for care of patients requiring any non-psychiatric intervention/s exist.

Indicator-101: Drug dependents are isolated in a nearby separate section of HCE as legally required.

Indicator-102: The treatment plans are periodically revised on the basis of regular patient monitoring/evaluation and the data on drug use trends in populations.

Indicator-103: Addiction treatment services are networked with other medical and social services for providing comprehensive care to the patients.

Indicator-104: Psycho-social interventions for rehabilitation of drug addicts and prevention of health and social consequences of addiction are operational.

Standard-26: Policies and procedures guide prevention of maltreatment of patient by the healthcare provider.

Indicator-105: SOPs to prevent maltreatment of patients by the care providers are practiced.

Standard-27: Policies and procedures guide the administration of anesthesia when required

Indicator-106: Documented SOPs for the administration of anesthesia exist.

Indicator-107: Informed consent for administration of anesthesia is obtained by the anesthetist.

Indicator-108: Periodic monitoring during anesthesia is regularly conducted.

1.8. Management of Medications (MOM).

Standard-28: Policies and procedures exist for the prescription of medications.

Indicator-109: Documented SOPs for prescription writing are available.

Indicator-110: SOPs are followed for prescription writing.

Indicator-111: Standardized drug treatment protocol is observed.

Standard-29: Policies and procedures guide the safe storage, dispensing and administration of medications.

Indicator-112: Medicines / disposables are stored as per guidelines.

Indicator-113: Expiry dates / shelf life are checked prior to administering, as applicable. **Indicator-114:** Labeling requirements are implemented.

Indicator-115: Dispensing/utilization are by an authorized person.

1.9. Patient Rights and Education (PRE).

Standard-30: Patients have the right to comprehensive and integrated mental health care that meets their Individual needs and achieves the best possible outcome in terms of their recovery/rehabilitation.

Indicator-116: Charter of rights and responsibilities is displayed and patients / families are guided.

Indicator-117: Patients/families are guided and facilitated in protecting patient's assets.

Standard-31: A documented process for obtaining patient and/or family consent exists for informed decision making about their care.

Indicator-118: The policy describes who can give consent when patient is incapable of Independent decision-making.

Indicator-119: Informed consent must be obtained from the patient / legal representative before the initiation of the examination / treatment/ management.

Standard-32: Patient and families have a right to information on expected costs.

Indicator-120: The patient/family is informed about the cost of treatment.

Indicator-121: There is uniform category specific pricing policy in a given setting.

Indicator-122: Patients and family are informed about the financial implications when a change in the treatment plan is necessitated due to patient's condition.

Standard-33: Patient Rights for Appeals and Complaints are respected.

Indicator-123: The HCE informs the patient of his/her right to express relevant concern or complain either verbally or in writing.

Indicator-124: There exists a documented complaint management process which is fair and timely.

Indicator-125: The HCE uses the results of complaints investigations as part of the quality improvement process.

Standard-34: Patient Rights regarding confidentiality of their ailment are respected.

Indicator-126: The HCE has documented SOPs to ensure confidentiality of patient identity and ailment

Indicator-127: The HCE ensures that patient identity is not disclosed to public through press or electronic media

1.10. Infection Control (IC)

Standard-35: The HCE has a comprehensive and coordinated infection control program aimed at reducing/eliminating risks to patients, visitors and care providers

Indicator-128: The HCE infection control plan is documented which aims at preventing and reducing risk of nosocomial infections

Indicator-129: The HCE has an Infection Control Committee

Indicator-130: The HCE has designated a qualified infection control nurse(s)/officer for this activity.

Indicator-131: The HCE has appropriate consumables, collection and handling systems, equipment and facilities for control of infection.

Indicator-132: All staff involved in the patient care, creation, handling and disposal of medical waste shall receive regular training and ongoing education in infection control and safe handling of medical waste.

SCHEDULE-VI

Responsibility of Management

Indicator-1:

The Tibb Clinic is identifiable with the name of Clinic, name of Healthcare Service Providers, professional qualification and National Council for Tibb registration number displayed on a signboard

Indicator-2:

The clinic is registered/licensed with the Islamabad Health Regulatory Authority (IHRA).

Indicator-3:

Door plate clearly displays name, professional qualifications and NCT registration number of Tabeeb/Tabeeba.

Indicator-4:

Consultation hours are displayed.

Indicator-5:

The clinic manager has requisite qualifications.

Indicator-6:

The NCT registration certificate of the Tabeeb/Tabeeba is displayed.

Indicator-7:

The size/premises of the Tibb clinics are as per the minimum requirement.

Indicator-8:

The clinic has adequate facilities for the comfort of the patients.

Indicator-9:

The clinic has adequate arrangements to maintain the privacy of patients during consultation/examination.

Facility Management and Safety (FMS)

Indicator-10:

The staff has knowledge about early detection and containment of fire and non-fire emergencies and arrangements available at Matab to combat these emergencies.

Human Resource Management (HRM)

Indicator-11:

Personal record/credentials in respect of all staff are maintained.

Information Management Systems (IMS)

Indicator-12:

The Clinic management has designated a person to maintain Clinic record and all entries in the patients record.

Assessment and Continuity of Care (ACC)

Indicator-13:

Only the Tibb services being provided at the clinic are displayed

Care of Patients (COP)

Indicator-14:

The Matab has essential arrangements to cater for emergency care according to Tibb-e-Unani.

Management of Medication (Remedies) (MOM)

Indicator-15:

Standards for prescription writing are followed with unique identification of every patient.

Indicator-16:

Record of prescriptions is available at the clinic.

Indicator-17:

Only the person(s) authorized by law can write the prescription.

Indicator-18:

Medicines are stored as per guidelines for safe storage.

Indicator-19:

Labelling requirements are implemented.

Indicator-20:

Authorize person to dispense the medicine in the clinic under supervision of registered Tabeeb/Tabeeba.

Patient Rights, Responsibilities and Education (PRE)

Indicator-21:

The situations requiring specific informed consent from a patient or family are listed at the clinic.

Indicator-22:

Patients have the right to ask for treatment's expenses.

Indicator-23:

Patients and families have a right to complain and a mechanism for complaint should exist to address the grievances.

Indicator-24:

The HCE Charter is displayed and patients/families are guided.

Infection Control (IC)

Indicator-25:

The clinic has arrangements for infection control aimed at preventing and reducing the risk of infections.

Dr. Quaid Saeed
(Secretary to the Board)